

EXHIBIT D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC., PELVIC REPAIR

5 SYSTEM PRODUCTS LIABILITY Master File No.
6 LITIGATION 2:12-MD-02327
7 MDL No. 2327

8 THIS DOCUMENT RELATES TO ALL
9 WAVE 5 AND SUBSEQUENT WAVES
10 CASES AND PLAINTIFFS:

 JOSEPH R. GOODWIN
 U.S. DISTRICT JUDGE

 Debbie Avant

 Case No. 2:12-cv-07413

 Patricia Bell

 Case NO. 2:12-cv-06750

 Patsy Frame

 Case No. 2:12-cv-07524

 Patricia Hosbrook

 Case No. 2:12-cv-07843

 Mary Alice Landeche

 Case No. 2:12-cv-07962

15 DEPOSITION OF STEVE GOLDWASSER, M.D.
16 PURSUANT TO NOTICE OF DEPOSITION

17 Taken on Behalf of the Plaintiffs

18 DATE TAKEN: July 1, 2017

19 TIME: 9:30 a.m. - 1:27 p.m.

20 PLACE: Courtyard Marriott Jacksonville Flagler
 Center

21 14402 Old St. Augustine Road
 Jacksonville, FL 32258

22 Examination of the witness taken before:

23 Stephanie Powers Cusimano

24 Registered Professional Reporter

25 Florida Professional Reporter

<p style="text-align: right;">Page 2</p> <p style="text-align: center;">A P P E A R A N C E S</p> <p>JOHN M. RESTAINO, ESQUIRE Restaino Law, LLC 1011 S. Josephine Street Denver, CO 80209 Appearing on behalf of Plaintiffs.</p> <p>ERIC RUMANEK, ESQUIRE Troutman Sanders LLP Bank of America Plaza Suite 5200 600 Peachtree Street, N.E. Atlanta, GA 30308-2216 Appearing on behalf of Defendant.</p>	<p style="text-align: right;">Page 4</p> <p style="text-align: center;">S T I P U L A T I O N</p> <p>It was stipulated and agreed by and between counsel for the respective parties, and the witness, that the reading and signing of the deposition by the witness not be waived.</p> <p style="text-align: center;">- - -</p> <p style="text-align: center;">STEVE GOLDWASSER, M.D., having been produced and first duly sworn as a witness, having responded, "Yes," testified as follows:</p> <p style="text-align: center;">DIRECT EXAMINATION</p> <p>BY MR. RESTAINO:</p> <p>Q Good morning, Dr. Goldwasser.</p> <p>A Good morning.</p> <p>Q We met informally before the depo started. My name is John Restaino. Stating the obvious, I'll be asking some questions today.</p> <p>To my understanding you've had your deposition taken before, correct?</p> <p>A Correct.</p> <p>Q So how many times?</p> <p>A I want to say maybe three times total. One in regards to this all litigation and so forth.</p> <p>Q So you're somewhat familiar with the process. And I think probably the two things that</p>
<p style="text-align: right;">Page 3</p> <p style="text-align: center;">I N D E X</p> <p>WITNESS: STEVE GOLDWASSER, M.D. DIRECT EXAMINATION BY MR. RESTAINO4 CROSS EXAMINATION BY MR. RUMANEK138 REDIRECT EXAMINATION BY MR. RESTAINO164 RECROSS EXAMINATION BY MR. RUMANEK177</p> <p style="text-align: center;">E X H I B I T S</p> <p>FOR IDENTIFICATION EXHIBIT 1 deposition notice7 EXHIBIT 2 Goldwasser CV10 EXHIBIT 3 general reliance list40 EXHIBIT 4 supplemental reliance list53 EXHIBIT 5 expert report54 EXHIBIT 6 Nilsson study55 EXHIBIT 7 TVT-Exact document70 EXHIBIT 8 Gynecare TVT70 EXHIBIT 9 TOMUS study73 EXHIBIT 10 Goldwasswer website printout84 EXHIBIT 11 '15 Bladder Dysfunction Report ..100 EXHIBIT 12 Koo/Gromley article106 EXHIBIT 13 FDA public healthupdate107</p>	<p style="text-align: right;">Page 5</p> <p>are of the most importance is the lady to your left, my right, is going to try to take down everything we say. Normal conversation some evening at a bar and we're talking and we're talking over each other's lines, that's just normal conversation, but today I'll try to extend to you the courtesy of waiting for that final period before I ask the next question. If you would do the same and try to wait for that question mark for her benefit. You understand that?</p> <p>A Correct.</p> <p>Q This is not an endurance test. This is not a memory test. If you need to refresh your memory or look at anything, that's absolutely allowable. And if the Coca-Cola exerts a physiological effect that you want to call time-out at any time, there's no set time that we take breaks.</p> <p>A Okay.</p> <p>Q Okay. If you don't understand any question I have, I can't imagine any of my questions being ambiguous, but if you can't, just please ask me and I'll try to rephrase it into something that's less legalistic and more normal.</p> <p>A Okay.</p>

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<p>1 MR. RUMANEK: Sarcasm doesn't show up on</p> <p>2 the record either.</p> <p>3 Q That being said, if you answer a question,</p> <p>4 it's going to be presumed that you understood the</p> <p>5 question --</p> <p>6 A Okay.</p> <p>7 Q -- does that make sense?</p> <p>8 A Yes.</p> <p>9 Q I don't think there's going to be any</p> <p>10 questions along this line, but I use the example of</p> <p>11 the length of this table and ask you to estimate it</p> <p>12 versus the length of my dining room, which, of</p> <p>13 course, would be a pure guess. No one wants you</p> <p>14 guessing, but if we can get an estimate where -- if</p> <p>15 and when necessary, that would be appropriate; do</p> <p>16 you understand that?</p> <p>17 A Yes.</p> <p>18 Q Okay. And any reason why today's</p> <p>19 deposition shouldn't be going forward?</p> <p>20 A Not at all.</p> <p>21 Q Do you have -- do you have patients,</p> <p>22 critical care, anything where you might have to</p> <p>23 leave early?</p> <p>24 A No, just a phone call away.</p> <p>25 Q Okay. I've asked the court reporter to</p>	<p>1 Q And regarding any pertinent germane</p> <p>2 documents in your possession regarding this</p> <p>3 litigation and your report, have you produced those?</p> <p>4 A Correct.</p> <p>5 MR. RUMANEK: Well, let me just make sure</p> <p>6 that's clear on the record. So we have brought</p> <p>7 some documents with us to the deposition this</p> <p>8 morning in response to the notice. We brought</p> <p>9 some extra copies of his report, I assume you</p> <p>10 have those. I've got a copy of the</p> <p>11 supplemental reliance list --</p> <p>12 MR. RESTAINO: I have that.</p> <p>13 MR. RUMANEK: -- that was served. I've</p> <p>14 also got a thumb drive, which, it's my</p> <p>15 understanding, contains the materials that are</p> <p>16 included on the supplemental reliance list, if</p> <p>17 you want that.</p> <p>18 MR. RESTAINO: Okay.</p> <p>19 MR. RUMANEK: That's it.</p> <p>20 MR. RESTAINO: Okay. As far as the thumb</p> <p>21 drive with the supplemental list, I'll speak</p> <p>22 off the record at the end of the deposition</p> <p>23 with the court reporter and perhaps we -- it</p> <p>24 would be best to have that sent along with the</p> <p>25 exhibits and the original to the Aylstock firm</p>
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<p>1 mark the deposition notice that was sent out, and</p> <p>2 this says deposition 1 and it's right in front of</p> <p>3 you at this time. Have you seen this before?</p> <p>4 (Exhibit 1 was marked for identification.)</p> <p>5 A Yes.</p> <p>6 Q And have you had a chance to go through it</p> <p>7 on your own or with anyone?</p> <p>8 A Yes.</p> <p>9 MR. RESTAINO: Eric, we've received</p> <p>10 objections to the notice.</p> <p>11 MR. RUMANEK: Yes.</p> <p>12 MR. RESTAINO: I'm not sure if you want to</p> <p>13 put them on the record, if we need to put them</p> <p>14 on the record. I'm not going to spend a lot of</p> <p>15 time going through this. There's, I think -- I</p> <p>16 think we have everything we need.</p> <p>17 MR. RUMANEK: No. I mean, I've got the</p> <p>18 objections that were filed. I don't think</p> <p>19 there's any reason to put them on the record.</p> <p>20 BY MR. RESTAINO:</p> <p>21 Q If we could just run through it quickly.</p> <p>22 I have a copy of your CV. To the best of your</p> <p>23 understanding, is the -- is the copy of your CV the</p> <p>24 most current?</p> <p>25 A Correct.</p>	<p>1 when everything is sent, if that's acceptable.</p> <p>2 MR. RUMANEK: And just -- let's go off the</p> <p>3 record.</p> <p>4 (Off-the-record discussion.)</p> <p>5 BY MR. RESTAINO:</p> <p>6 Q We've covered that.</p> <p>7 Other than what has been produced, do you</p> <p>8 have any other Ethicon products in your possession?</p> <p>9 A No.</p> <p>10 Q And have you produced time sheets, records</p> <p>11 for billing, invoices, anything like that?</p> <p>12 A Not for this.</p> <p>13 Q Okay. Do you have them?</p> <p>14 A No.</p> <p>15 Q Number 14 is documents related to your</p> <p>16 involvement with Ethicon's professional education,</p> <p>17 including PowerPoints, course materials, outlines.</p> <p>18 Do you have any of those, and, if so, did you</p> <p>19 produce those?</p> <p>20 A No, I don't have any -- I don't.</p> <p>21 Q And number 17 is any correspondence,</p> <p>22 transcripts or statements, documents between you and</p> <p>23 any governmental agency. Does anything like that</p> <p>24 exist?</p> <p>25 A No.</p>

<p style="text-align: right;">Page 10</p> <p>1 Q I think that's good enough.</p> <p>2 Now, those -- the one that you've been</p> <p>3 given is the one that's been marked as the exhibit,</p> <p>4 so we're not going to come back to that, but there</p> <p>5 will be some that we'll come back to, and I'll try</p> <p>6 to remember to say, that one you might want to keep</p> <p>7 readily available, but -- so there's others that</p> <p>8 we'll just go ahead and put to the side.</p> <p>9 I'm going to ask the court reporter to</p> <p>10 mark as Plaintiff 2 the copy of your CV that I was</p> <p>11 provided.</p> <p>12 (Exhibit 2 was marked for identification.)</p> <p>13 BY MR. RESTAINO:</p> <p>14 Q And, Doctor, as we discussed earlier, this</p> <p>15 is the most current, or at least the closest to</p> <p>16 being the most current version of your CV?</p> <p>17 A Yeah. Yes, it is.</p> <p>18 Q And do you have any publications that have</p> <p>19 been accepted for -- I should ask, any submissions</p> <p>20 that have been accepted for publication that are</p> <p>21 pending?</p> <p>22 A No.</p> <p>23 Q You did your undergrad school -- schooling</p> <p>24 at UC San Diego?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 12</p> <p>1 Q -- though, you engage in teaching,</p> <p>2 correct?</p> <p>3 A Correct.</p> <p>4 Q Okay. And how was your fellowship in</p> <p>5 urogynecology and reconstructive pelvic surgery</p> <p>6 different from your residency in obstetrics and</p> <p>7 gynecology?</p> <p>8 A Well, it was a focus specifically on</p> <p>9 urogynecology as opposed to obstetrics and general</p> <p>10 gynecology.</p> <p>11 Q During your fellowship, for example, did</p> <p>12 you -- were you on call to deliver babies?</p> <p>13 A Yes.</p> <p>14 Q Okay. So it was still gyn- -- obstetrics</p> <p>15 also?</p> <p>16 A Well, that was an outside, you know,</p> <p>17 moonlighting type of activity, but it wasn't a</p> <p>18 formal part of the fellowship.</p> <p>19 Q Okay. Just a way to make some extra money</p> <p>20 and survive?</p> <p>21 A Yeah, exactly. Exactly.</p> <p>22 Q So during your fellowship, here the</p> <p>23 emphasis was on urogynecological and pelvic</p> <p>24 reconstructive surgery itself?</p> <p>25 A Correct.</p>
<p style="text-align: right;">Page 11</p> <p>1 Q And then medical school was at Tulane?</p> <p>2 A Correct.</p> <p>3 Q A little bit difference of humidity.</p> <p>4 A Yes, a few degrees.</p> <p>5 Q And then your residency was at the</p> <p>6 University of Tennessee at Memphis, correct?</p> <p>7 A Correct.</p> <p>8 Q Followed by a fellowship?</p> <p>9 A Correct.</p> <p>10 Q Now, what I was a little confused with is</p> <p>11 looking at fellowship as listed on the front page,</p> <p>12 on the right side of fellowship, it says Clinical</p> <p>13 Instructor, underneath that Urogynecology and</p> <p>14 Reconstructive Pelvic Surgery. Were you, in fact,</p> <p>15 in the position of a clinical instructor while you</p> <p>16 were doing your fellowship?</p> <p>17 A You know, I believe that when we were</p> <p>18 doing the fellowships back then, we were teaching</p> <p>19 the residents, so I guess we were considered</p> <p>20 clinical instructors. I think that's where that</p> <p>21 comes from.</p> <p>22 Q That's normal for --</p> <p>23 A Yeah.</p> <p>24 Q -- trainees as fellows --</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q But there's also medicine involved in that</p> <p>2 specialty, correct?</p> <p>3 MR. RUMANEK: Object to form.</p> <p>4 Q Let me rephrase. That might have been one</p> <p>5 of those ambiguous questions.</p> <p>6 You're a physician and a surgeon, correct?</p> <p>7 A Correct.</p> <p>8 Q And there are conditions in urogynecology</p> <p>9 and gynecology that can be treated medically --</p> <p>10 A Correct.</p> <p>11 Q -- or with pelvic -- or physical therapy?</p> <p>12 A Correct.</p> <p>13 Q Testing can be done that is not surgical</p> <p>14 in nature --</p> <p>15 A Correct.</p> <p>16 Q -- like urodynamic testing?</p> <p>17 A Correct.</p> <p>18 Q Have you -- were you trained in that?</p> <p>19 A Yes.</p> <p>20 Q Trained in uroflowmetry?</p> <p>21 A Correct.</p> <p>22 Q Post-voiding residual measurements?</p> <p>23 A Correct.</p> <p>24 Q Cystometric testing?</p> <p>25 A Correct.</p>

<p style="text-align: right;">Page 14</p> <p>1 Q Leak point pressure measuring?</p> <p>2 A Correct.</p> <p>3 Q Pressure flow studies?</p> <p>4 A Correct.</p> <p>5 Q These are various urodynamic studies that</p> <p>6 you were trained in, have expertise in?</p> <p>7 A Correct.</p> <p>8 Q A couple of these might be considered</p> <p>9 invasive procedures. Do you consider them invasive?</p> <p>10 MR. RUMANEK: Object to the form.</p> <p>11 Q Let me retract that. Do you consider any</p> <p>12 of those procedures to be substantially invasive</p> <p>13 procedures?</p> <p>14 MR. RUMANEK: Object to the form.</p> <p>15 A Not surgical procedures, but invasive,</p> <p>16 yes.</p> <p>17 Q Dangerous to the patient?</p> <p>18 MR. RUMANEK: Object to the form.</p> <p>19 A It's a broad question, but --</p> <p>20 Q Okay. I'll withdraw it.</p> <p>21 Now, there are subspecialties within the</p> <p>22 specialty of gynecology, correct?</p> <p>23 A Correct.</p> <p>24 Q Gynecological oncology, did you receive</p> <p>25 specific formal training in that as part of your</p>	<p style="text-align: right;">Page 16</p> <p>1 fetal medicine?</p> <p>2 A No.</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 Q And then not the last, but the, say, final</p> <p>5 one is the urogynecological and pelvic</p> <p>6 reconstructive surgical subspecialty, and that you</p> <p>7 did receive training in, correct?</p> <p>8 A Correct.</p> <p>9 Q And do you consider yourself an expert in</p> <p>10 urogynecology and pelvic reconstructive surgery?</p> <p>11 A Yes.</p> <p>12 MR. RUMANEK: No objection.</p> <p>13 Q I saw five publications is listed in your</p> <p>14 CV; is that correct?</p> <p>15 A I believe so.</p> <p>16 Q And, now, is that a representative sample</p> <p>17 of your publications or the publications in total?</p> <p>18 A I believe that's in total.</p> <p>19 Q Okay. So I notice that your first</p> <p>20 publication was in 1999 and was titled Randomized</p> <p>21 Comparison Of Oral Misoprostol Versus Foley Catheter</p> <p>22 And Xylocaine For Induction Of Labor At Term. Did I</p> <p>23 read that correctly?</p> <p>24 A I'm trying to find it, but it sounds</p> <p>25 right.</p>
<p style="text-align: right;">Page 15</p> <p>1 residency and/or fellowship?</p> <p>2 A In residency.</p> <p>3 Q Okay. But not in your fellowship?</p> <p>4 A Correct.</p> <p>5 Q Do you consider yourself an expert in</p> <p>6 gynecologic oncology?</p> <p>7 MR. RUMANEK: Object to the form.</p> <p>8 A No.</p> <p>9 Q Maternal fetal medicine, another</p> <p>10 subspecialty?</p> <p>11 A Correct.</p> <p>12 Q And did you receive training in that in</p> <p>13 your residency and/or fellowship?</p> <p>14 A Residency, correct.</p> <p>15 Q And are you an expert in maternal fetal</p> <p>16 medicine?</p> <p>17 MR. RUMANEK: Object to the form.</p> <p>18 A No.</p> <p>19 Q Reproductive endocrinology and</p> <p>20 infertility, is that another subspecialty?</p> <p>21 A Correct.</p> <p>22 Q And did you receive training in that in</p> <p>23 residency and/or fellowship?</p> <p>24 A Residency.</p> <p>25 Q Are you considered an expert in maternal</p>	<p style="text-align: right;">Page 17</p> <p>1 Q I think it's the third page, bottom --</p> <p>2 right above Abstracts and Procedures.</p> <p>3 A Oh, yeah, yeah. Okay. I see it.</p> <p>4 Q And what I'll do now is I'll just work</p> <p>5 myself up with these publications. When you say a</p> <p>6 randomized comparison, was this a randomized study?</p> <p>7 A Yes.</p> <p>8 Q I guess to be clear for the record, was</p> <p>9 this a randomized controlled trial?</p> <p>10 A I'm trying to remember exactly. Let me</p> <p>11 read it over again. Yeah, the control was the Foley</p> <p>12 catheter group, correct.</p> <p>13 Q Okay. Now, this was published when you</p> <p>14 were a fellow; is that correct?</p> <p>15 A No, resident.</p> <p>16 Q Oh, okay. Sorry. I'm getting ahead of</p> <p>17 myself.</p> <p>18 And this has nothing to do with vaginal</p> <p>19 mesh?</p> <p>20 A Correct.</p> <p>21 Q And then in 2000 you published Suprapubic</p> <p>22 Bladder Drainage After Extraperitoneal Cystotomies;</p> <p>23 did I read that correctly?</p> <p>24 A Correct.</p> <p>25 Q Was that a case report, a case series, or</p>

<p style="text-align: right;">Page 18</p> <p>1 review of the literature, do you recall?</p> <p>2 A I don't recall.</p> <p>3 Q Was this published during your fellowship?</p> <p>4 A Yes.</p> <p>5 Q And again, this doesn't have anything to</p> <p>6 do with vaginal mesh?</p> <p>7 A No.</p> <p>8 MR. RUMANEK: Let me just note, the first</p> <p>9 publication it says is 1999. I think he asked</p> <p>10 you was that published during your residency or</p> <p>11 fellowship. Was that --</p> <p>12 THE WITNESS: You know --</p> <p>13 MR. RUMANEK: I'm just looking at the</p> <p>14 dates.</p> <p>15 THE WITNESS: It's probably '98. It's</p> <p>16 probably -- well, no, it may have been</p> <p>17 published after I graduated, because it was a</p> <p>18 project, a senior project, and I graduated in</p> <p>19 '98, and so it was probably published in '99.</p> <p>20 BY MR. RESTAINO:</p> <p>21 Q Okay. The next one up, moving up, is</p> <p>22 Failure Of Intraoperative Cystoscopy To Identify</p> <p>23 Partial Ureteral Obstruction, and that, I believe,</p> <p>24 was also published in 2000?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 20</p> <p>1 looking back at our data from fellowship in terms of</p> <p>2 surgical outcomes from that type of procedure, if I</p> <p>3 recall correctly.</p> <p>4 Q Okay. Does it have anything to do with</p> <p>5 vaginal mesh?</p> <p>6 A No.</p> <p>7 Q And then the -- the top one published in</p> <p>8 2002 is Predicting Postoperative Voiding Efficiency</p> <p>9 After Operation For Incontinence And Prolapse</p> <p>10 published in 2002, correct?</p> <p>11 A Correct.</p> <p>12 Q And, once again, was this a review of</p> <p>13 literature or case reports or the result of an</p> <p>14 actual clinical trial?</p> <p>15 A I believe this was an actual trial that we</p> <p>16 did.</p> <p>17 Q And do you know if it was a randomized</p> <p>18 controlled trial, a cohort case control, or any</p> <p>19 other form of epidemiological study?</p> <p>20 A I do not recall.</p> <p>21 Q Now, the best I could ascertain, this is</p> <p>22 your last publication in the peer-reviewed medical</p> <p>23 literature; is that correct?</p> <p>24 A Correct.</p> <p>25 Q Now, I saw under Abstracts and</p>
<p style="text-align: right;">Page 19</p> <p>1 Q As you sit here today, do you remember if</p> <p>2 that was a case report, a case series, or review of</p> <p>3 the literature?</p> <p>4 A It was a case report.</p> <p>5 Q So in a case report, I'm just jumping</p> <p>6 ahead now, is a report of a single case that might</p> <p>7 be of interest; is that correct?</p> <p>8 A Correct.</p> <p>9 Q And there's no randomization involved?</p> <p>10 A No.</p> <p>11 Q No control?</p> <p>12 A Correct.</p> <p>13 Q No placebo?</p> <p>14 A Correct.</p> <p>15 Q Moving up, the next article is High</p> <p>16 Uterosacral Vaginal Vault Suspension With Fascial</p> <p>17 Reconstruction For Vaginal Repair Of Enterocoele And</p> <p>18 Vaginal Vault Prolapse. Did I attempt to read that</p> <p>19 correctly?</p> <p>20 A You got it. Pretty good.</p> <p>21 Q It's -- the coffee hasn't kicked in yet.</p> <p>22 Now, again, was this a case report or</p> <p>23 review of the literature to the best of your</p> <p>24 recollection?</p> <p>25 A This is actually -- this was basically</p>	<p style="text-align: right;">Page 21</p> <p>1 Proceedings, the bottom one on that third page</p> <p>2 titled A Simplified Technique For Apical Fixation Of</p> <p>3 Grafts In Repair Of Anterior Genital Prolapse, The</p> <p>4 Anterior Perirectal Pass; did I read that correctly?</p> <p>5 A Correct.</p> <p>6 Q Now, the grafts that you're referring to</p> <p>7 there, that is native issue or mesh or both?</p> <p>8 A Mesh.</p> <p>9 Q Now, was this presented as a poster in a</p> <p>10 -- in this meeting?</p> <p>11 A I believe that was presented as -- that</p> <p>12 was an oral presentation actually.</p> <p>13 Q Okay. Following that meeting, it did not</p> <p>14 turn into a full-blown peer-reviewed medical</p> <p>15 article -- did it turn into a full-blown medical</p> <p>16 article published in the peer-reviewed literature?</p> <p>17 A No.</p> <p>18 Q And at this meeting did you hold yourself</p> <p>19 out to your colleagues as an expert in the use of</p> <p>20 transvaginal mesh?</p> <p>21 A Yes.</p> <p>22 Q This was a regional conference?</p> <p>23 A Correct.</p> <p>24 Q And have you ever presented at a national</p> <p>25 conference and hold yourself out as an expert in</p>

<p style="text-align: right;">Page 22</p> <p>1 transvaginal mesh?</p> <p>2 A No, I have not presented at a national</p> <p>3 conference.</p> <p>4 Q Other than your own institution, has any</p> <p>5 academic institution invited you to come in and give</p> <p>6 a guest lecture on the use of vaginal mesh,</p> <p>7 specifically DVT -- DVT and DVT-Exact [sic]?</p> <p>8 A No.</p> <p>9 MR. RESTAINO: Something I should have put</p> <p>10 on the record --</p> <p>11 MR. RUMANEK: Okay. Are you saying DVT or</p> <p>12 T --</p> <p>13 MR. RESTAINO: T.</p> <p>14 MR. RUMANEK: TVT, okay.</p> <p>15 BY MR. RESTAINO:</p> <p>16 Q Something I should have put -- we should</p> <p>17 have discussed earlier on, throughout your report</p> <p>18 and in questioning, today your -- your testimony is</p> <p>19 limited to the two devices, the transvaginal TVT</p> <p>20 mesh and the TVT-Exact; is that correct?</p> <p>21 A Correct.</p> <p>22 MR. RUMANEK: I just want to object just</p> <p>23 to the extent that you've already asked him</p> <p>24 about -- some questions about prolapse, so I</p> <p>25 think his report is limited to those things.</p>	<p style="text-align: right;">Page 24</p> <p>1 A No.</p> <p>2 Q And have you had formal training and --</p> <p>3 and I'll be happy to discuss my definition of that,</p> <p>4 if need be, if you don't understand. Have you had</p> <p>5 any formal training in epidemiology?</p> <p>6 A No.</p> <p>7 Q You're not degreed as an epidemiologist?</p> <p>8 A Correct.</p> <p>9 Q Have you ever personally designed a</p> <p>10 randomized controlled trial?</p> <p>11 A No.</p> <p>12 Q And do you understand that the strength of</p> <p>13 a randomized controlled trial is the randomization,</p> <p>14 which greatly diminishes the possibility of bias?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 A Yes.</p> <p>17 Q Of the other epidemiological studies, and</p> <p>18 I'm not playing word games, including cohort or case</p> <p>19 control or case series, case report, they don't</p> <p>20 involve randomization, correct?</p> <p>21 A Correct.</p> <p>22 Q Do you consider the randomized controlled</p> <p>23 trial to be the gold standard of epidemiology?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A I mean, it's the highest level of</p>
<p style="text-align: right;">Page 23</p> <p>1 His testimony, depending on the questions</p> <p>2 asked, may or may not be.</p> <p>3 MR. RESTAINO: I understand. And I'm just</p> <p>4 trying to clear this up.</p> <p>5 Q There is a product that has been described</p> <p>6 as TVT-Retropubic; am I correct?</p> <p>7 A Correct.</p> <p>8 Q When your report and when I and hopefully</p> <p>9 you say TVT as compared to TVT-Exact, can we agree</p> <p>10 that we're referring to TVT-Retropubic?</p> <p>11 A Well, they're both retropubic, but yes.</p> <p>12 Q But they're two different devices?</p> <p>13 A Correct.</p> <p>14 Q I just want to make it clear for the</p> <p>15 record and so -- for everyone.</p> <p>16 And also for the court reporter, has been</p> <p>17 pointed out, and it was pointed out the last time I</p> <p>18 took deposition too, I have a tendency to say, for</p> <p>19 whatever reason, DVT. I'm far more experienced with</p> <p>20 deep vein thrombosis than I am with trans- -- so</p> <p>21 when I say DVT, that's just senile and dementia</p> <p>22 setting in.</p> <p>23 Doctor, have you -- have you ever been</p> <p>24 invited to be a visiting professor on any topic at</p> <p>25 any academic institution?</p>	<p style="text-align: right;">Page 25</p> <p>1 evidence, but --</p> <p>2 Q Fair enough. And as a resident and</p> <p>3 fellow, did you rely upon published randomized</p> <p>4 controlled trials to further your education?</p> <p>5 MR. RUMANEK: Object to the form.</p> <p>6 A It's part of the educational process.</p> <p>7 Q Okay. And do you consider yourself an</p> <p>8 expert in the design -- the epidemiological design</p> <p>9 of a randomized controlled trial?</p> <p>10 A No.</p> <p>11 Q Why not?</p> <p>12 A I don't pursue that. I mean, I don't know</p> <p>13 what else to tell you.</p> <p>14 Q Did you ever design a cohort</p> <p>15 epidemiological study?</p> <p>16 A No.</p> <p>17 Q During residency, fellowship, did you</p> <p>18 utilize cohort studies in your education?</p> <p>19 MR. RUMANEK: Object to the form.</p> <p>20 A I would assume so.</p> <p>21 Q You said with the randomized controlled</p> <p>22 trial, that it was the highest form of</p> <p>23 epidemiological evidence. Would you consider the</p> <p>24 cohort study to be a rung below the RCT?</p> <p>25 A Correct.</p>

<p style="text-align: right;">Page 26</p> <p>1 Q And do you consider yourself an expert in 2 the design of an epidemiological cohort study?</p> <p>3 A No.</p> <p>4 Q During residency, fellowship, or private 5 practice, have you ever designed a case controlled 6 study?</p> <p>7 A No.</p> <p>8 Q During training did you utilize case 9 controlled studies or read and study case controlled 10 studies as part of your education?</p> <p>11 A Yes.</p> <p>12 Q Do you consider the case controlled study 13 to be epidemiologically weaker than the cohort 14 study?</p> <p>15 A Yes, it is.</p> <p>16 Q Today do you rely upon case control 17 studies to assist you in your decision making as a 18 physician and surgeon?</p> <p>19 MR. RUMANEK: Object to the form.</p> <p>20 A As one of many things I rely on, correct.</p> <p>21 Q And do you consider yourself an expert in 22 the design of a case control epidemiological study?</p> <p>23 A No.</p> <p>24 Q Now, we touched upon, I'll get into a 25 little more detail here, what is a case report?</p>	<p style="text-align: right;">Page 28</p> <p>1 series, but I'd say probably more than one would be 2 considered a series.</p> <p>3 Q Again, to the best of your knowledge, 4 understanding no formal training in epidemiology, 5 but case series, once again, does not involve 6 randomization, correct?</p> <p>7 A Correct.</p> <p>8 Q And it does not involve a placebo?</p> <p>9 A Correct.</p> <p>10 Q And there's typically not a controlled 11 element to it, correct?</p> <p>12 A Agree.</p> <p>13 Q It's publication of observations and 14 nothing more, correct?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 A Yes.</p> <p>17 Q It might fight it out with the expert 18 opinions, but, once again, it's at the bottom of the 19 epidemiological rung strength, would you agree?</p> <p>20 A Agree.</p> <p>21 Q Okay. And as you sit here today, do you 22 have -- do you understand the difference between an 23 incidence rate and a prevalence rate?</p> <p>24 A The exact definition escapes me, but I 25 know that there is a difference in the two. So</p>
<p style="text-align: right;">Page 27</p> <p>1 A A case report is where you simply make an 2 observation in your practice, for example, and you 3 report upon what you found and -- your observations 4 basically.</p> <p>5 Q And as I believe we touched upon, in a -- 6 your typical case report, there isn't a control; is 7 that correct?</p> <p>8 A Correct.</p> <p>9 Q And there typically is not a placebo, 10 correct?</p> <p>11 A Correct.</p> <p>12 Q Would you agree that, epidemiologically 13 speaking, the case report is the weakest of all 14 evidence?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 A I think expert opinion may really be the 17 weakest, if I recall, but it's down there on the 18 lower part of the food chain, I'd say.</p> <p>19 Q Now, if you report on a patient that you 20 see an effect in, I'm paraphrasing you, and correct 21 me if I'm wrong, that is a case report, correct?</p> <p>22 A Correct.</p> <p>23 Q If you were to report on five of those 24 patients, that would be a case series?</p> <p>25 A I don't know the exact definition of a</p>	<p style="text-align: right;">Page 29</p> <p>1 yeah, more or less I do.</p> <p>2 Q Okay. Now, have you had any formal 3 training in pathology since medical school or 4 residency?</p> <p>5 A No.</p> <p>6 Q During your residency and fellowship, did 7 you rely upon pathological analyses?</p> <p>8 MR. RUMANEK: Object to the form.</p> <p>9 A During residence and fellowship, we came 10 across them. I mean, it was case-by-case basis, but 11 to some degree.</p> <p>12 Q Well, I don't mean to be confusing and I'm 13 not playing a word game. If, for example, during 14 fellowship you were involved in a surgery involving 15 a serious ovarian tumor, would you be required to 16 take the tissue to the laboratory, look under the 17 microscope, and make the ultimate pathological 18 diagnosis of what it is?</p> <p>19 A No.</p> <p>20 Q You rely upon a pathologist to do that?</p> <p>21 A Correct. They have to have a job, right?</p> <p>22 Q Well, do you consider yourself an expert 23 in the field of pathology?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A No.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q Have you had any formal training in 2 material sciences, whether undergrad or medical 3 school or post grad?</p> <p>4 A No.</p> <p>5 Q Once again, as a resident, surgeon, and 6 fellow, did you rely upon published material, 7 science, studies?</p> <p>8 MR. RUMANEK: Object to the form.</p> <p>9 A In what?</p> <p>10 Q In -- well, I'll choose mesh. At that 11 time if there was a publication on the material 12 science of mesh published, did you -- would you 13 review that and interpret that article to your own 14 satisfaction?</p> <p>15 A Yeah, to some degree.</p> <p>16 Q Would you rely upon published material, 17 science, studies to assist you in making -- your 18 final decision making?</p> <p>19 MR. RUMANEK: Object to the form.</p> <p>20 A Potentially.</p> <p>21 Q Do you consider yourself an expert in the 22 field of material sciences?</p> <p>23 MR. RUMANEK: Object to the form.</p> <p>24 A No.</p> <p>25 Q Have you ever conducted any animal</p>	<p style="text-align: right;">Page 32</p> <p>1 Q Have you ever removed a TVT mesh product 2 from a woman?</p> <p>3 A Yes.</p> <p>4 Q Can you estimate how many you've removed?</p> <p>5 MR. RUMANEK: And you're referring to just 6 the TVT specifically?</p> <p>7 MR. RESTAINO: Yes.</p> <p>8 A I would say probably less than 20.</p> <p>9 Q When you've removed them, have you asked 10 for electro-microscopic analysis of the mesh itself?</p> <p>11 A No.</p> <p>12 Q Do you have any formal training in 13 electro-microscopy?</p> <p>14 A No.</p> <p>15 Q As a practicing physician and surgeon, 16 will you read and perhaps rely upon published EM 17 studies regarding any materials germane to your 18 specialty?</p> <p>19 MR. RUMANEK: Object to the form.</p> <p>20 A I don't know that I necessarily rely upon 21 them, but I come across them in the literature.</p> <p>22 Q And do you consider yourself an expert in 23 electro-microscopic analyses?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A No.</p>
<p style="text-align: right;">Page 31</p> <p>1 research involving polypropylene mesh?</p> <p>2 A No.</p> <p>3 Q And I'll get a little bit more specific 4 just for the record, have you considered -- have you 5 conducted animal research involving TVT mesh?</p> <p>6 A Have I conducted it, no.</p> <p>7 Q Yes. Have you conducted any 8 epidemiological study involving TVT mesh?</p> <p>9 A No.</p> <p>10 Q Have you conducted any animal research 11 involving TVT-Exact mesh?</p> <p>12 A No.</p> <p>13 Q Have you conducted any epidemiological 14 study involving TVT-Exact mesh?</p> <p>15 A No.</p> <p>16 Q Have -- I think I asked that. 17 Has Ethicon ever approached you about 18 designing for them an animal study to look at 19 polypropylene mesh?</p> <p>20 A No.</p> <p>21 Q Have they ever approached you to and 22 consulted with you -- have they approached with you, 23 consulted with you, asking you to design any form of 24 polypropylene mesh to be used in women?</p> <p>25 A No.</p>	<p style="text-align: right;">Page 33</p> <p>1 Q Now, my understanding is you're being paid 2 \$500 an hour for your time to review medical records 3 and draft written reports; is that correct?</p> <p>4 A Correct.</p> <p>5 Q And then \$600 an hour for in-town 6 depositions?</p> <p>7 A Correct.</p> <p>8 Q I don't know where you live. Is this 9 considered in town or out of town?</p> <p>10 A In town.</p> <p>11 Q Okay. And you charge \$6,000 per day for 12 out-of-town depositions?</p> <p>13 A Correct.</p> <p>14 Q \$5,000 per day for in-town depositions --</p> <p>15 A Correct.</p> <p>16 Q -- in-town trial testimony? I'm sorry.</p> <p>17 MR. RUMANEK: Yeah, I just -- let me just 18 say that his fees are reflected in the report. 19 And I'll just -- to the extent that the 20 questions may be somewhat confusing, that's set 21 forth in his expert report. Go ahead.</p> <p>22 Q Counsel raises a very good point. These 23 were written with my not understanding what in town 24 and out of town was. Let's just clear that up, that 25 right now here is -- in south Jacksonville is</p>

<p style="text-align: right;">Page 34</p> <p>1 considered in town. Anywhere outside of 2 Jacksonville would be out of town? 3 A Correct. 4 Q Okay. You mentioned that you had given a 5 previous deposition in -- involving the mesh 6 litigation? 7 A Correct. 8 Q And was that in town or out of town? 9 A In town. 10 MR. RUMANEK: He was sitting right here 11 actually. 12 Q Now, have you testified in any mesh 13 trials? 14 A No. 15 MR. RUMANEK: And let me just say, because 16 I don't want the record to be -- I think when 17 he was referring to testifying in mesh, he was 18 referring to as an expert witness. He's also 19 been deposed in mesh cases before, but I just 20 want to make sure that distinction was clear. 21 MR. RESTAINO: I believe I understood 22 that -- 23 MR. RUMANEK: Okay. 24 MR. RESTAINO: -- so I think the record's 25 clear on that.</p>	<p style="text-align: right;">Page 36</p> <p>1 A A long time ago. I think so. I remember 2 no cell phone reception out there. It was a long 3 time ago. 4 MR. RESTAINO: Off the record. 5 (Off-the-record discussion.) 6 BY MR. RESTAINO: 7 Q Now, for your preparation for the 8 deposition, your meeting last night, are you going 9 to be charging Ethicon? 10 A Yes. 11 Q I'm correct in assuming that you charge 12 Ethicon for all the work that you do as an expert 13 witness for them? 14 A Correct. 15 Q So if you were sent or you found a new 16 medical article that's on point to your role as an 17 expert, did you ever read that article in 18 preparation for your report or your discussion or 19 today and not charge for it? 20 MR. RUMANEK: Object to the form. 21 A I'm sure at some point, yes. 22 Q Now, you mentioned that you have a general 23 reliance list, which we're going to go ahead and 24 mark, and a supplemental reliance list, correct? 25 A Correct.</p>
<p style="text-align: right;">Page 35</p> <p>1 BY MR. RESTAINO: 2 Q And just to make sure, earlier on when I 3 asked you if you had given depositions before, I 4 believe you answered in this litigation, but as 5 explained by Counsel, we have an understanding of 6 what was meant. 7 Now, did -- did you undergo any 8 preparation for today's deposition? 9 A Yes. 10 Q And briefly explain without -- if you met 11 with Counsel, I'm not entitled to know what you 12 discussed, but I'm entitled to know if you met and 13 for how long and where it was, that kind of stuff. 14 A Okay. 15 Q So can you briefly describe what you did 16 to prepare for today's deposition. 17 A I've reviewed my report. I reviewed part 18 of the literature contained within my report and 19 literature on my reliance list. I met with Counsel 20 for probably an hour and a half yesterday evening. 21 Q Did you meet in an office or at a 22 restaurant? 23 A In this room. 24 Q In this room. I ate at Clark's Fish Camp 25 last night. Have you been there?</p>	<p style="text-align: right;">Page 37</p> <p>1 Q Can you tell me what they are. 2 A Well, I'm not exactly sure what the 3 supplemental one is, but the general reliance list, 4 excuse me, is -- is the literature that was 5 available to me to look over and review as part of 6 the preparation of writing the report. 7 Q Is it a list of materials for you to look 8 over in preparation for your report that you relied 9 upon that was given to you or is this something that 10 you've created and found the articles, added the 11 articles yourself? 12 MR. RUMANEK: Object to the form. 13 A A combination of the two. 14 Q You need some water? 15 A No, I'm good. 16 Q In the -- for your expert report, there's 17 a list of company witness depositions listed -- 18 A Correct. 19 Q -- is there not? And you've read those? 20 A Yes. 21 Q And typically, because lawyers can talk, 22 those depositions tend to be several pages long, 23 will you agree upon that? 24 A I agree. 25 Q And did you sit and read any of those</p>

<p style="text-align: right;">Page 38</p> <p>1 depositions and not charge for that time?</p> <p>2 A I don't recall. I would say that it was</p> <p>3 probably part of my lump sum of hours and research</p> <p>4 to my best recollection.</p> <p>5 Q Do you have a record of how many hours you</p> <p>6 have spent, let's break it down, first preparing for</p> <p>7 and drafting/writing this current expert report?</p> <p>8 A Yes.</p> <p>9 Q And can you estimate how many hours that</p> <p>10 was?</p> <p>11 A Again, it would be an estimate. I would</p> <p>12 say probably -- with the review of all the</p> <p>13 literature, actually writing the report, I'd say</p> <p>14 probably in the 30- to 40-hour range.</p> <p>15 Q And in preparation for your reports, would</p> <p>16 you spend time reviewing or, for example -- or as an</p> <p>17 example, PubMed to find germane articles?</p> <p>18 A Yes.</p> <p>19 Q And then you would download those articles</p> <p>20 and read the article?</p> <p>21 A Correct.</p> <p>22 Q Okay. And then charge Ethicon for that,</p> <p>23 correct?</p> <p>24 MR. RUMANEK: Object to form.</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 40</p> <p>1 Q So in that 30 or 40 hours, did you -- have</p> <p>2 you broken it down to X number of hours searching,</p> <p>3 downloading, reading medical records versus how many</p> <p>4 hours actually writing the report?</p> <p>5 A No, I did not separate those out.</p> <p>6 Q It's all included in one?</p> <p>7 A Correct.</p> <p>8 Q Okay. And the same thing for your expert</p> <p>9 report, there -- is there a specific line listing X</p> <p>10 hours writing expert report?</p> <p>11 A No.</p> <p>12 Q Okay. When were you first contacted about</p> <p>13 being an expert on behalf of Ethicon in the mesh</p> <p>14 litigation?</p> <p>15 A I'd say in the last portion of 2016.</p> <p>16 Q And who contacted you?</p> <p>17 A Counsel for Ethicon.</p> <p>18 Q And have you ever worked with counsel for</p> <p>19 Ethicon in the past in any capacity?</p> <p>20 A Not that I recall.</p> <p>21 Q Okay. Now, I'll go ahead and have the</p> <p>22 court reporter mark as the next exhibit the general</p> <p>23 reliance list.</p> <p>24 (Exhibit 3 was marked for identification.)</p> <p>25</p>
<p style="text-align: right;">Page 39</p> <p>1 Q Okay. Were you given by anyone articles</p> <p>2 that you did not yourself find and download?</p> <p>3 A Yes.</p> <p>4 Q And who gave you those articles?</p> <p>5 A Counsel for Ethicon.</p> <p>6 Q And did you review those articles?</p> <p>7 A To some degree.</p> <p>8 Q Did you charge Ethicon for that review?</p> <p>9 A Yes.</p> <p>10 Q Is -- do you have or do you plan on having</p> <p>11 an invoice that is specific to, for example, how</p> <p>12 much time you spent reviewing the medical articles</p> <p>13 as cited in your expert report, your general</p> <p>14 reliance, and your supplemental reliance?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 A I have a -- can you repeat the question</p> <p>17 one more time?</p> <p>18 Q I'll try to make it clearer in that you</p> <p>19 said that you estimated there was approximately 30</p> <p>20 to 40 hours that you have spent. Was that in</p> <p>21 response to preparing your expert report, correct?</p> <p>22 A Correct.</p> <p>23 Q That's different from the time you spent</p> <p>24 preparing for this deposition?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 41</p> <p>1 MR. RESTAINO: Counsel, I've got one for</p> <p>2 you in case you need it.</p> <p>3 MR. RUMANEK: Thanks.</p> <p>4 BY MR. RESTAINO:</p> <p>5 Q Now, as per the title itself, are you</p> <p>6 relying upon the materials within the document to</p> <p>7 support your general opinions in this regard?</p> <p>8 A Correct.</p> <p>9 Q Okay. And as far as actually, I'll try to</p> <p>10 make it clear, typing up the document, did you type</p> <p>11 this up or did someone else?</p> <p>12 A I typed it up.</p> <p>13 MR. RUMANEK: He's talking about the</p> <p>14 reliance list --</p> <p>15 THE WITNESS: Oh.</p> <p>16 MR. RUMANEK: -- not your expert report.</p> <p>17 A No, I did not type the reliance list.</p> <p>18 Q Do you know who did?</p> <p>19 A No.</p> <p>20 Q Did you give whomever the listing of what</p> <p>21 should be in your general reliance list?</p> <p>22 A No.</p> <p>23 Q Have you gone through the general reliance</p> <p>24 list to make sure that everything that's in there</p> <p>25 you are relying upon in supporting your expert</p>

<p style="text-align: right;">Page 42</p> <p>1 opinion?</p> <p>2 MR. RUMANEK: Object to the form.</p> <p>3 A I've -- I've --</p> <p>4 MR. RUMANEK: No, I just want to make</p> <p>5 clear. So part of what was included in the --</p> <p>6 on the reliance list were the materials that</p> <p>7 were provided to Dr. Goldwasser by counsel.</p> <p>8 MR. RESTAINO: Understood.</p> <p>9 MR. RUMANEK: Okay. I just want to make</p> <p>10 sure that's --</p> <p>11 BY MR. RESTAINO:</p> <p>12 Q And was there anything provided to you</p> <p>13 that you reviewed and say, no, I disagree with this</p> <p>14 and I'm not relying upon it?</p> <p>15 A Yeah, I mean, I came across articles that</p> <p>16 I didn't necessarily rely on, but, I mean, there was</p> <p>17 no formal discussion over it. It's all part of the</p> <p>18 research going into the report.</p> <p>19 Q Okay. Now --</p> <p>20 MR. RUMANEK: And I just want to make --</p> <p>21 again, I just want to make sure this is clear</p> <p>22 on the record just so -- so you're</p> <p>23 understanding.</p> <p>24 So some of the materials that were</p> <p>25 provided, you may characterize as not</p>	<p style="text-align: right;">Page 44</p> <p>1 down and I estimated there's approximately 20</p> <p>2 medical articles on every page. And doing just some</p> <p>3 really crude calculations using my slide ruler,</p> <p>4 there's over 900 medical records on the general</p> <p>5 reliance list.</p> <p>6 A Yeah, probably --</p> <p>7 Q Did you review those 900 articles?</p> <p>8 A Not in detail.</p> <p>9 Q Did you review them at all?</p> <p>10 A Yes.</p> <p>11 Q Each one?</p> <p>12 A No.</p> <p>13 Q Any way of knowing which ones are listed</p> <p>14 in there, in your general reliance that you haven't</p> <p>15 looked at?</p> <p>16 A No.</p> <p>17 Q As far as the expert report, that has</p> <p>18 other references or citations specifically in it,</p> <p>19 correct?</p> <p>20 A Repeat that one more time.</p> <p>21 Q Within your expert report, as we'll get</p> <p>22 to, you actually, then, have a reference for certain</p> <p>23 points, correct?</p> <p>24 A Correct.</p> <p>25 Q And those references are also listed in</p>
<p style="text-align: right;">Page 43</p> <p>1 supporting his opinions. You just said</p> <p>2 supporting your opinions, and I just -- it's</p> <p>3 materials that were provided to him to</p> <p>4 consider. Whether or not somebody may</p> <p>5 characterize them as supporting or not</p> <p>6 supporting, I just --</p> <p>7 MR. RESTAINO: Okay.</p> <p>8 MR. RUMANEK: I just didn't want that</p> <p>9 question to be unclear.</p> <p>10 MR. RESTAINO: I appreciate that. Thank</p> <p>11 you.</p> <p>12 BY MR. RESTAINO:</p> <p>13 Q Is -- from my perspective, if I sit down</p> <p>14 and read everything in there, it's your general</p> <p>15 reliance list, so my assumption is that you are</p> <p>16 relying upon the information in there as -- to</p> <p>17 support the bases of your expert opinion. So if</p> <p>18 there's something in the document that you disagree</p> <p>19 with, how would I know that unless we go through</p> <p>20 every document?</p> <p>21 A You wouldn't.</p> <p>22 Q Okay. Now, that general reliance list is,</p> <p>23 from what I -- when I looked at it and counted, 68</p> <p>24 pages in length, including the cover page, and it</p> <p>25 includes 46 pages of medical records. So I counted</p>	<p style="text-align: right;">Page 45</p> <p>1 there. How did you decide which ones you would use</p> <p>2 and cite or reference in your expert report versus</p> <p>3 those that you wouldn't use?</p> <p>4 MR. RUMANEK: And let me just -- also just</p> <p>5 before you make an objection, the reliance list</p> <p>6 specifically says "general reliance list in</p> <p>7 addition to materials referenced in the</p> <p>8 report." They may be exact -- all reference,</p> <p>9 but to the extent that there are additional</p> <p>10 references in the report that are not on the</p> <p>11 reliance list, it's certainly possible.</p> <p>12 MR. RESTAINO: Thank you. I don't think</p> <p>13 there are.</p> <p>14 MR. RUMANEK: Okay. It may not be in</p> <p>15 there.</p> <p>16 MR. RESTAINO: I think they're consistent,</p> <p>17 but, of course, there's a lot more in here.</p> <p>18 BY MR. RESTAINO:</p> <p>19 Q How did you determine the existence of the</p> <p>20 medical records that are listed in your general</p> <p>21 reliance list and your supplemental reliance list?</p> <p>22 MR. RUMANEK: Object to form.</p> <p>23 A How did I determine -- say that one more</p> <p>24 time. How did I determine what?</p> <p>25 Q How did you determine their existence?</p>

<p style="text-align: right;">Page 46</p> <p>1 How did you find each article that's listed in your 2 expert report, your general reliance report, your 3 supplemental report?</p> <p>4 A Well, when I was doing a literature 5 search, I would look up certain topics, come across 6 articles, review them, see if it was something I 7 wanted to include in my report, and if so, it would 8 wind up in the reliance list. So it was a -- just a 9 process.</p> <p>10 Q Okay.</p> <p>11 MR. RUMANEK: And again, on the -- just 12 there were also materials that were provided to 13 Dr. Goldwasser by counsel that are on the 14 reliance list as well.</p> <p>15 Q If you look at the first article in the 16 general reliance list, top of the third page, I 17 believe it's the Aaron LA and Buchwald D article; is 18 that correct?</p> <p>19 A Correct.</p> <p>20 Q And it's titled Diffuse -- Chronic Diffuse 21 Musculoskeletal Pain, Fibromyalgia, And Co-Morbid 22 Unexplained Clinical Conditions; is that correct?</p> <p>23 A Correct.</p> <p>24 Q Now, that is one of the articles that's 25 not cited in your expert report?</p>	<p style="text-align: right;">Page 48</p> <p>1 in this litigation?</p> <p>2 MR. RUMANEK: Object to the form.</p> <p>3 A No, I mean, I don't think it's part of my 4 report, so I don't think I was relying upon it to 5 support any of my -- my opinions in the report.</p> <p>6 Q Can you estimate for an article like this 7 and the articles in your expert report and the 8 remainder in the general supplemental listing how 9 long it takes to read such a medical article?</p> <p>10 A Well, it's hard to give you a good 11 guesstimate. I mean, it could range anywhere from 12 reviewing the abstract in a minute to actually 13 delving into the whole methods and details of the -- 14 of the article. And you said it's 12 pages, that 15 may take, I don't you know, ten, 15 minutes or so to 16 get through it.</p> <p>17 Q Okay. If you turn to page 47 of your 18 general reliance list --</p> <p>19 A I don't think they're numbered.</p> <p>20 Q Are they numbered?</p> <p>21 A Oh, no. Unh-unh.</p> <p>22 THE WITNESS: Is yours numbered?</p> <p>23 Q How did I get page 47?</p> <p>24 A I'm going to count back now and we'll find 25 it.</p>
<p style="text-align: right;">Page 47</p> <p>1 A Correct.</p> <p>2 Q Did you read this article?</p> <p>3 A Yeah, I actually did.</p> <p>4 Q And how long did it take for you to read 5 it?</p> <p>6 A You know, I honestly could not give you 7 even a guesstimate.</p> <p>8 MR. RESTAINO: Let's go off the record for 9 one moment.</p> <p>10 (Off-the-record discussion.)</p> <p>11 BY MR. RESTAINO:</p> <p>12 Q Now, this is published in Best Practice & 13 Research Clinical Rheumatology, correct?</p> <p>14 A Correct.</p> <p>15 Q And how did you find this article?</p> <p>16 A I don't recall whether this was one of the 17 ones -- it was probably one of the ones provided 18 that, you know, I could have the option of looking 19 through, obviously, but I don't recall specifically 20 pulling this one myself.</p> <p>21 Q Okay. Now, this article, I'll represent 22 to you, if you don't recall, is -- it is 12 pages 23 long with five pages of references. Do you recall 24 as you sit here what it is about this article that 25 you are relying upon for -- to support your opinions</p>	<p style="text-align: right;">Page 49</p> <p>1 Q Well, how did I come up with page 47? It 2 just showed up in my computer as the pdf page number 3 there on the left. I apologize for that.</p> <p>4 A I think I'm on approximately page 47. 5 Anything in particular?</p> <p>6 Q Yes, there's an article -- there's a 7 study, 2003, and then in parenthesis 14-day Rabbit 8 Study.</p> <p>9 A These are all -- my page 47 here are all 10 internal documents. Is that -- is it an internal 11 document?</p> <p>12 Q I believe so.</p> <p>13 A 14 Day-rabbit Study. I don't see a 14-day 14 Rabbit Study in here.</p> <p>15 Q Let me see. Oh, here's what I did. If 16 you -- it should be in the title of the -- the upper 17 left, it's called Production Materials. Prior to 18 that it was all called Medical Records.</p> <p>19 A Yeah, these are production materials.</p> <p>20 Q The very first one is dated -- of the 21 production materials.</p> <p>22 A Here we go.</p> <p>23 MR. RUMANEK: I'll just note, I think the 24 earlier section was Medical Literature.</p> <p>25 A Okay. Now I see it. 14-day Rabbit Study,</p>

<p style="text-align: right;">Page 50</p> <p>1 okay.</p> <p>2 Q Okay. Do you recall reading this study?</p> <p>3 A Not specifically.</p> <p>4 Q Did you read it?</p> <p>5 A I don't recall.</p> <p>6 Q Did you read the -- in the production</p> <p>7 materials, did you read each of the materials that's</p> <p>8 listed there?</p> <p>9 A I don't recall. I reviewed a tremendous</p> <p>10 amount of information in this, and I couldn't</p> <p>11 specifically tell you.</p> <p>12 Q And so as you sit here today, you have no</p> <p>13 recollection about this 14-day Rabbit Study?</p> <p>14 A Now, have you -- do you have it and I can</p> <p>15 take a look through it?</p> <p>16 Q No, I don't have specific questions. It's</p> <p>17 more along the lines of just a general question.</p> <p>18 Just there's 900 medical articles listed.</p> <p>19 A Right.</p> <p>20 Q There are -- in the 13 pages of -- or, I</p> <p>21 mean, in the production materials, there's 13 pages</p> <p>22 of production materials, and I'm just trying to get</p> <p>23 to how much time did you spend reviewing all of</p> <p>24 this.</p> <p>25 A Right. Right.</p>	<p style="text-align: right;">Page 52</p> <p>1 and -- you know, so some of these things I may have</p> <p>2 seen outside of, you know, specifically putting</p> <p>3 together a report that may be in here. But no, I</p> <p>4 mean, back then I didn't specifically charge Ethicon</p> <p>5 for reviewing those because there wasn't anything</p> <p>6 that I engaged in at the time.</p> <p>7 Q Okay. That just saved a lot of questions</p> <p>8 because I was going to ask why would you watch ten</p> <p>9 videos of human anatomy after medical school,</p> <p>10 fellowship, residency, private practice, and now</p> <p>11 you're going to sit back and watch -- has the</p> <p>12 anatomy changed since --</p> <p>13 A No, but I watched everything on You Tube</p> <p>14 and I ran out of stuff to do, you know. No, it has</p> <p>15 not changed.</p> <p>16 Q Let's go ahead and --</p> <p>17 MR. RUMANEK: Once again, I will note that</p> <p>18 sarcasm does not show up on a written</p> <p>19 transcript.</p> <p>20 Q I will mark as -- I believe we're up to 4,</p> <p>21 your -- just to get it out of the way, the</p> <p>22 supplemental general reliance list in addition to</p> <p>23 materials referenced in report MDL wave number 5.</p> <p>24 MR. RESTAINO: Eric, another tree.</p> <p>25 MR. RUMANEK: This is 4.</p>
<p style="text-align: right;">Page 51</p> <p>1 Q Now, one aspect of it is you testified</p> <p>2 that your charge -- you've charged Ethicon between</p> <p>3 30 to -- for 30 to 40 hours. If we spent ten</p> <p>4 minutes on 900 medical articles, we're into the</p> <p>5 hundreds of hours.</p> <p>6 A Well, I can take a look back and tell you</p> <p>7 exactly how much time I've spent. I'm giving you,</p> <p>8 you know, my best guess, but, yeah, no, it is what</p> <p>9 it is.</p> <p>10 Q Okay. In the -- the section of Production</p> <p>11 Materials -- and I wish I had picked up that there</p> <p>12 weren't page numbers on this, but in glancing</p> <p>13 through it and looking at the various production</p> <p>14 materials in your general reliance, I noted that ten</p> <p>15 of the materials listed there -- I'll represent to</p> <p>16 you that ten of them are listed as anatomy videos.</p> <p>17 Do you recall seeing that?</p> <p>18 A I don't recall going through every single</p> <p>19 anatomy video, but I did review some anatomy videos.</p> <p>20 Q Can you estimate how long each video is?</p> <p>21 A No. Some of the videos that I actually</p> <p>22 saw for anatomy videos, if we're talking about the</p> <p>23 same thing, are things that, you know, over the past</p> <p>24 what, 18 years I've looked at videotapes of, you</p> <p>25 know, anatomy that were part of the training courses</p>	<p style="text-align: right;">Page 53</p> <p>1 (Exhibit 4 was marked for identification.)</p> <p>2 THE WITNESS: Can we take a break? I have</p> <p>3 a question for you.</p> <p>4 (Recess from 10:19 a.m. to 10:20 a.m.)</p> <p>5 BY MR. RESTAINO:</p> <p>6 Q Just to close this section, Doctor, did</p> <p>7 you charge Ethicon for the time you spent reviewing</p> <p>8 anatomy videos?</p> <p>9 A Not if they weren't part of this directly.</p> <p>10 Q Can you tell us briefly, what is the</p> <p>11 supplemental general reliance list?</p> <p>12 A I honestly do not know exactly what that</p> <p>13 refers to.</p> <p>14 Q I share that with you. I'll represent</p> <p>15 that it's also -- I guess it doesn't have page</p> <p>16 numbers, but it's also 68 pages long and -- but at</p> <p>17 the same -- starts with the same medical articles</p> <p>18 and I started getting lost.</p> <p>19 A Okay.</p> <p>20 Q So that will save us some time too.</p> <p>21 A Okay.</p> <p>22 Q Now, let's move on to your actual expert</p> <p>23 report, which I'll go ahead and ask the court</p> <p>24 reporter to mark as next in line, which I think</p> <p>25 we're up to 5?</p>

<p style="text-align: right;">Page 54</p> <p>1 (Exhibit 5 was marked for identification.)</p> <p>2 BY MR. RESTAINO:</p> <p>3 Q Okay. And, Doctor, we've previously</p> <p>4 discussed TVT and TVT-Exact and we have agreement</p> <p>5 about what each of those terms means, correct?</p> <p>6 A Correct.</p> <p>7 Q Okay. Now, I've asked you how much time</p> <p>8 you've spent on this. The first very sentence says</p> <p>9 your report contains your "general opinions</p> <p>10 regarding design, safety, and efficacy of the</p> <p>11 Gynecare TVT and TVT-Exact"; is that correct?</p> <p>12 A Correct.</p> <p>13 Q And what do you mean when you say your</p> <p>14 general expert opinions?</p> <p>15 A It is -- it's a general report on these</p> <p>16 two devices. That's what I mean, just -- I don't</p> <p>17 know. I don't know what else to say about that word</p> <p>18 "general" in particular.</p> <p>19 Q Okay. For the record, there isn't any</p> <p>20 case-specific opinions regarding any one woman</p> <p>21 listed in the report, correct?</p> <p>22 A Correct.</p> <p>23 Q Give me one second. Okay. I had a page</p> <p>24 wrong -- numbered wrong, I'm sorry. I apologize.</p> <p>25 If you would turn to page 3 of your</p>	<p style="text-align: right;">Page 56</p> <p>1 correct?</p> <p>2 A I'd agree.</p> <p>3 Q And as we previously described, the case</p> <p>4 series, along with expert opinions, is the weakest</p> <p>5 of epidemiological evidence, correct?</p> <p>6 A With expert opinion, yeah, correct.</p> <p>7 Q And this case series doesn't have a</p> <p>8 control group, correct?</p> <p>9 A Correct.</p> <p>10 Q And there was no randomization involved,</p> <p>11 correct?</p> <p>12 A Correct.</p> <p>13 Q And there was no blinding described by --</p> <p>14 of the patients or the researchers, correct?</p> <p>15 A Correct.</p> <p>16 Q And if you look at -- on the second page</p> <p>17 in Figure 1, you have the typical flowchart that</p> <p>18 we'll see in such a -- such a study, and they</p> <p>19 started with 90 women that were operated on with TVT</p> <p>20 in Figure 1, correct?</p> <p>21 A Correct.</p> <p>22 Q And then following down, 11 of the women</p> <p>23 over the 17 years died; is that correct?</p> <p>24 A Correct.</p> <p>25 Q Leaving 79 women eligible for the study,</p>
<p style="text-align: right;">Page 55</p> <p>1 report, the top paragraph, the last sentence, you</p> <p>2 write, "In a 17-year follow-up study on the TVT</p> <p>3 procedure, Nilsson," N-i-l-s-s-o-n, "et al., found</p> <p>4 that over 90 percent of the women were objectively</p> <p>5 continent, 87 percent were subjectively cured or</p> <p>6 significantly improved," period, followed by the</p> <p>7 citation. Did I read that correctly?</p> <p>8 A Yes.</p> <p>9 MR. RESTAINO: Now, if -- I'll go ahead</p> <p>10 and have that marked as -- as Exhibit 6.</p> <p>11 (Exhibit 6 was marked for identification.)</p> <p>12 BY MR. RESTAINO:</p> <p>13 Q And, Doctor, if you would look at the</p> <p>14 Abstract and Methods on the first page, they write</p> <p>15 here that, "A cohort of 90 women operated upon with</p> <p>16 the TVT procedure at 3 Nordic centers has been</p> <p>17 prospectively followed for 17 years." Did I read</p> <p>18 that correctly?</p> <p>19 A Yes.</p> <p>20 Q Now, as used here, the word "cohort"</p> <p>21 actually refers to the group of patients and not a</p> <p>22 cohort study, correct?</p> <p>23 A Correct.</p> <p>24 Q Okay. Now, this is a -- in fact, a</p> <p>25 prospective case series of women receiving TVT mesh,</p>	<p style="text-align: right;">Page 57</p> <p>1 but of those, five women developed impaired mental</p> <p>2 capacity and 16 women were lost to follow-ups,</p> <p>3 correct?</p> <p>4 A Correct.</p> <p>5 Q So the analysis and conclusions reported</p> <p>6 by Nilsson in this case series is based upon a total</p> <p>7 of 58 women with no controls; is that correct?</p> <p>8 A Correct.</p> <p>9 Q In your expert report, you don't describe</p> <p>10 this study as a case series of 58 women, do you?</p> <p>11 A No, not specifically.</p> <p>12 Q And if you turn to the fourth page of the</p> <p>13 case series, and the right column, it's page -- it</p> <p>14 doesn't have a page listing, but --</p> <p>15 A Is it Table 1 that you're referring to?</p> <p>16 Q There's -- Table 3 is on the left.</p> <p>17 A Okay.</p> <p>18 Q On the right, the first full paragraph,</p> <p>19 they write there that, "A weakness of the present</p> <p>20 study is the fact that urodynamics were not</p> <p>21 performed, as the women did not consent to such an</p> <p>22 invasive examination," period. Did I read that</p> <p>23 correctly?</p> <p>24 A Correct.</p> <p>25 Q And we discussed urodynamics as you went</p>

<p style="text-align: right;">Page 58</p> <p>1 through in your training, correct?</p> <p>2 A Correct.</p> <p>3 Q And while urodynamic studies are invasive,</p> <p>4 it's not a dangerous invasive procedure, correct?</p> <p>5 A Not necessarily.</p> <p>6 MR. RUMANEK: Object to form.</p> <p>7 Q Did you ever have a patient die undergoing</p> <p>8 urodynamic studies?</p> <p>9 A No, but you can have patients who develop</p> <p>10 infections. There's certain risks involved with any</p> <p>11 procedure.</p> <p>12 Q Any invasive procedure specifically --</p> <p>13 A Correct.</p> <p>14 Q -- agreed?</p> <p>15 Okay. So what we have here that you're</p> <p>16 relying upon is a 58-patient case series, no</p> <p>17 randomization, no placebo, no blinding, and no</p> <p>18 objective urodynamic testing, correct?</p> <p>19 A Correct. And I'd also add that I'm</p> <p>20 relying on it in the context of prior studies, you</p> <p>21 know, of these women being followed. I believe</p> <p>22 there's some seven -- a seven-year study, a 12-year</p> <p>23 study looking at the same cohort of women as they</p> <p>24 aged in terms of their symptomatic response to the</p> <p>25 procedure, and also my own clinical experience.</p>	<p style="text-align: right;">Page 60</p> <p>1 seen in association with urogenital prolapse surgery</p> <p>2 that have alerted the FDA might be caused by the</p> <p>3 mesh itself, correct?</p> <p>4 MR. RUMANEK: Object to the form.</p> <p>5 A It's possible.</p> <p>6 MR. RUMANEK: It speaks for itself. Let</p> <p>7 me -- and if I object, make sure I finish the</p> <p>8 objection.</p> <p>9 Q And then he writes, "As long as a type 1</p> <p>10 material is used, the complications could be the</p> <p>11 result of improper training of the surgeon,</p> <p>12 resulting in inappropriate surgical technique or</p> <p>13 choosing the wrong indication or wrong patient for</p> <p>14 graft procedure," correct?</p> <p>15 A Correct.</p> <p>16 Q Again, not a definitive statement.</p> <p>17 MR. RUMANEK: Object to form. Speaks for</p> <p>18 itself.</p> <p>19 A Correct.</p> <p>20 Q And they could have easily have said, as</p> <p>21 long as type 1 material is used, the complications</p> <p>22 could be the result of the type 1 material itself?</p> <p>23 MR. RUMANEK: Object to the form. It</p> <p>24 speaks for itself. Calls for speculation.</p> <p>25 A Correct.</p>
<p style="text-align: right;">Page 59</p> <p>1 Q Sure. On this same page in the fourth</p> <p>2 paragraph -- fourth full paragraph, it starts with,</p> <p>3 "Mesh complications"; do you see that?</p> <p>4 A Correct.</p> <p>5 Q And they write there, "The mesh</p> <p>6 complications seen in association with urogenital</p> <p>7 prolapse surgery that have alerted the FDA might not</p> <p>8 be caused by the mesh material itself. As long as a</p> <p>9 type 1 material is used, the complications could be</p> <p>10 the result of improper training of the surgeon,</p> <p>11 resulting in an inappropriate surgical technique or</p> <p>12 choosing the wrong indication or wrong patient for</p> <p>13 the graft procedure." Did I read that correctly?</p> <p>14 A Correct.</p> <p>15 Q Now, that's not a very definitive</p> <p>16 statement in the sense that in the first sentence,</p> <p>17 "The mesh complications seen in association with</p> <p>18 urogenital prolapse surgery that have alerted the</p> <p>19 FDA might not be caused by the mesh material</p> <p>20 itself," correct?</p> <p>21 MR. RUMANEK: Object to the form. It</p> <p>22 speaks for itself.</p> <p>23 A Correct.</p> <p>24 Q And the flip side to that is that they</p> <p>25 could just as easily write, the mesh complications</p>	<p style="text-align: right;">Page 61</p> <p>1 Q Now, this paper, which you're relying</p> <p>2 upon, if you turn to the last page, right above the</p> <p>3 References, you see Conflicts of Interest, and they</p> <p>4 have the letters CGN and CF have acted as</p> <p>5 consultants for Astellas, A-s-t-e-l-l-a-s, Ethicon,</p> <p>6 and Pfizer, correct?</p> <p>7 A Correct.</p> <p>8 Q And CGN is actually the lead author of the</p> <p>9 study, C.G. Nilsson, and CF is the senior or last</p> <p>10 author, C. Falconer, correct?</p> <p>11 A Correct.</p> <p>12 Q And so this case series of 58 women upon</p> <p>13 which you're relying upon, two of them were -- are</p> <p>14 consultants for Ethicon, the defendant in this</p> <p>15 litigation, correct?</p> <p>16 MR. RUMANEK: Object to the form.</p> <p>17 A Correct.</p> <p>18 Q And in recent years, medical articles --</p> <p>19 medical journals have required that authors disclose</p> <p>20 conflicts of interest because of concerns about</p> <p>21 bias; is that correct?</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 A Correct.</p> <p>24 Q So if you were training in the '90s, were</p> <p>25 conflict-of-interest disclosures required when you</p>

<p style="text-align: right;">Page 62</p> <p>1 were a resident?</p> <p>2 MR. RUMANEK: Object to the form.</p> <p>3 A I don't recall. I don't recall.</p> <p>4 Q I don't either.</p> <p>5 A I don't know when it came about.</p> <p>6 Q It wasn't in the '80s.</p> <p>7 A It wasn't in the '80s.</p> <p>8 Q Okay.</p> <p>9 MR. RUMANEK: Are you -- your phone, I</p> <p>10 just am seeing it's -- are you recording it</p> <p>11 or --</p> <p>12 MR. RESTAINO: Sorry. I can't take in all</p> <p>13 those words -- oh, Siri came on.</p> <p>14 (Off-the-record discussion.)</p> <p>15 BY MR. RESTAINO:</p> <p>16 Q Now, returning to the expert report,</p> <p>17 the -- your report, as we've now discussed, is on</p> <p>18 Ethicon's TVT-Retropubic device and the TVT-Exact</p> <p>19 device; is that correct?</p> <p>20 A Correct.</p> <p>21 Q And today you're not -- won't be offering</p> <p>22 any opinions on any other device; is that correct?</p> <p>23 MR. RUMANEK: Object to the form.</p> <p>24 A Correct.</p> <p>25 Q Okay. Have you heard of Boston</p>	<p style="text-align: right;">Page 64</p> <p>1 Q And do you know why it was recalled?</p> <p>2 A I believe -- purely just off of recall, I</p> <p>3 believe that there were some infections or</p> <p>4 wound-healing issues.</p> <p>5 Q Have you studied the FDA analysis of the</p> <p>6 ProtoGen adverse event reports in preparation for</p> <p>7 being an expert regarding TVT and TVT-Exact?</p> <p>8 MR. RUMANEK: Object to the form.</p> <p>9 A No.</p> <p>10 Q And are -- as you sit here today, are you</p> <p>11 familiar with any similarities between the predicate</p> <p>12 device and the TVT and the TVT-Exact?</p> <p>13 MR. RUMANEK: Object to the form.</p> <p>14 A You know, I don't remember the details of</p> <p>15 the ProtoGen device to be able to answer that</p> <p>16 question.</p> <p>17 Q Okay. And you are in private practice,</p> <p>18 correct?</p> <p>19 A Correct.</p> <p>20 Q You have an office with a staff where you</p> <p>21 see patients?</p> <p>22 A Correct.</p> <p>23 Q Do you allow detailing by pharmaceutical</p> <p>24 representatives?</p> <p>25 A Pharmaceutical representatives, yes.</p>
<p style="text-align: right;">Page 63</p> <p>1 Scientific's ProtoGen device?</p> <p>2 A Yes.</p> <p>3 Q And what do you know about that?</p> <p>4 A Nothing in particular.</p> <p>5 Q I'll represent to you that it was approved</p> <p>6 in 1996. And are you familiar with the term</p> <p>7 "predicate device"?</p> <p>8 A Correct. Yes.</p> <p>9 Q Do you know that the Boston Scientific</p> <p>10 ProtoGen device as approved in 1996 is the predicate</p> <p>11 device for subsequent transvaginal mesh devices?</p> <p>12 MR. RUMANEK: Object to the form.</p> <p>13 A No, I wasn't aware of that.</p> <p>14 Q Do you know there's no clinical testing of</p> <p>15 the TVT or the TVT-Exact because they follow the</p> <p>16 predicate device?</p> <p>17 MR. RUMANEK: Object to the form.</p> <p>18 A There was some clinical testing.</p> <p>19 Q Premarket approval?</p> <p>20 MR. RUMANEK: Object to the form.</p> <p>21 A Yeah, I believe so.</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 Q Do you know that the -- that the Boston</p> <p>24 Scientific ProtoGen device was recalled in 1999?</p> <p>25 A Yes.</p>	<p style="text-align: right;">Page 65</p> <p>1 Q Hypothetically speaking, if a</p> <p>2 pharmaceutical representative came to your office on</p> <p>3 Monday and said they're finishing Phase 3 trials of</p> <p>4 a new drug that has a 95 percent cure rate for</p> <p>5 incontinence, would that be something you'd be</p> <p>6 interested in hearing about?</p> <p>7 A Sure.</p> <p>8 Q Incontinence is a major part of your</p> <p>9 practice, correct?</p> <p>10 A Correct.</p> <p>11 Q And it's a major problem that women and</p> <p>12 men, but in your specialty women, suffer from,</p> <p>13 correct?</p> <p>14 A Correct.</p> <p>15 Q So a drug with a 95 percent cure rate</p> <p>16 would be something of interest?</p> <p>17 A Correct.</p> <p>18 Q If, however, the representative said, now,</p> <p>19 there's a 95 percent cure rate, but there's also an</p> <p>20 association of ovarian cancer, would you want to</p> <p>21 know about that?</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 A Yeah, I mean, I'd be interested in the</p> <p>24 details of it, yeah.</p> <p>25 Q Ovarian cancer can be a fatal disease,</p>

<p style="text-align: right;">Page 66</p> <p>1 correct?</p> <p>2 A Correct.</p> <p>3 Q Would you want to know what the incidence</p> <p>4 was of ovarian cancer in the study?</p> <p>5 MR. RUMANEK: Object to the form.</p> <p>6 A Ovarian cancer in a drug study?</p> <p>7 Q Yes.</p> <p>8 A Yeah, that, amongst all the data that went</p> <p>9 into it, I mean, the general -- the context of which</p> <p>10 this came about, correct.</p> <p>11 Q As a physician, is the incidence of an</p> <p>12 adverse event associated with a drug something that</p> <p>13 you'd want to know before you prescribed that drug</p> <p>14 to your patients?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 A Amongst other things, correct.</p> <p>17 Q Okay. Now, when adverse events are</p> <p>18 reported to the FDA by physicians, patients, or</p> <p>19 whomever, do you know that that report is also sent</p> <p>20 on to the pharmaceutical or medical device company?</p> <p>21 MR. RUMANEK: Object to the form.</p> <p>22 A Yeah, I believe I've heard that that's the</p> <p>23 chain of events.</p> <p>24 Q And if a -- an adverse event is reported</p> <p>25 by a physician such as yourself and sent directly to</p>	<p style="text-align: right;">Page 68</p> <p>1 Q Now, if you did a review of the literature</p> <p>2 on incidence rate of a drug that you use in your</p> <p>3 practice and you were lecturing at your hospital or</p> <p>4 a national proceeding, you can only lecture on the</p> <p>5 incidence of adverse events that's published or</p> <p>6 given to you in one form or another, you don't have</p> <p>7 all that data, do you?</p> <p>8 MR. RUMANEK: Object to the form.</p> <p>9 A Okay. So you're saying -- repeat that</p> <p>10 again.</p> <p>11 Q Sure. If -- if the pharmaceutical company</p> <p>12 or medical device company gets reports -- all the</p> <p>13 reports of the adverse events that are sent to the</p> <p>14 FDA, then they have knowledge of X. And if you're</p> <p>15 invited to give a talk on the adverse events</p> <p>16 associated with that drug or that medical device and</p> <p>17 you review the medical literature for what has been</p> <p>18 reported, you have some fraction of X, would you</p> <p>19 agree?</p> <p>20 MR. RUMANEK: Object to the form.</p> <p>21 A Well, there's -- there's multiple sources</p> <p>22 where you can get this information from. I mean,</p> <p>23 it's one piece of information. I mean, there may be</p> <p>24 separate case studies or randomized controlled</p> <p>25 studies where these adverse events become apparent.</p>
<p style="text-align: right;">Page 67</p> <p>1 the pharmaceutical company or a medical device</p> <p>2 company, they have the duty to send that to the FDA?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 Mischaracterizes the regulation.</p> <p>5 A I don't know specifically what their</p> <p>6 obligation is.</p> <p>7 Q Okay. Do you have an opinion as to</p> <p>8 whether a pharmaceutical company and/or a medical</p> <p>9 device company should disclose incidences of known</p> <p>10 adverse events to physicians who are prescribing or</p> <p>11 utilizing their products?</p> <p>12 MR. RUMANEK: Object to the form.</p> <p>13 A It's hard to say. I mean, that's a very</p> <p>14 broad question. I mean, there's information out in</p> <p>15 the environment. And I think that if I'm</p> <p>16 specifically interested in that, then yes, I'm going</p> <p>17 to find it. I mean, I don't necessarily always</p> <p>18 think it's the company's responsibility, though.</p> <p>19 Q If the company's receiving the adverse</p> <p>20 event reports from the FDA, then they would have a</p> <p>21 handle on the total number of adverse events being</p> <p>22 reported to the FDA on that drug or that product,</p> <p>23 correct?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A To some degree.</p>	<p style="text-align: right;">Page 69</p> <p>1 I mean, it's all within the context of what you're</p> <p>2 looking at.</p> <p>3 Q Is it your understanding that the total</p> <p>4 number of adverse events that are reported to the</p> <p>5 FDA and a pharmaceutical company is available in the</p> <p>6 medical literature?</p> <p>7 MR. RUMANEK: Object to the form.</p> <p>8 A I don't know specifically about that.</p> <p>9 Q Okay.</p> <p>10 MR. RESTAINO: Can we take just a moment</p> <p>11 or two? I could use some water actually.</p> <p>12 MR. RUMANEK: Sure.</p> <p>13 (Recess from 10:40 a.m. to 10:48 a.m.)</p> <p>14 BY MR. RESTAINO:</p> <p>15 Q In preparation for writing your expert</p> <p>16 report and/or your deposition today, did you review</p> <p>17 the instructions for use manuals with the</p> <p>18 TVT-Retropubic and TVT-Exact products?</p> <p>19 A Yes.</p> <p>20 Q Okay. Did you see in either document a</p> <p>21 listing of adverse events associated with the</p> <p>22 devices?</p> <p>23 A Yes.</p> <p>24 Q Did you see the listing of incidence of</p> <p>25 adverse event associated with any adverse event?</p>

<p style="text-align: right;">Page 70</p> <p>1 A I don't recall. Do you have the document?</p> <p>2 Q I do. Let's go ahead and mark the</p> <p>3 TVT-Exact as, I think, 7.</p> <p>4 (Exhibit 7 was marked for identification.)</p> <p>5 MR. RESTAINO: And then we'll mark the</p> <p>6 Gynecare TVT as next.</p> <p>7 (Exhibit 8 was marked for identification.)</p> <p>8 MR. RUMANEK: Let me just say these don't</p> <p>9 have Bates numbers on them, so I'll just state</p> <p>10 on the record, Exhibit 7 looks like it's -- at</p> <p>11 the bottom of the first page, it says Ethicon,</p> <p>12 Inc., 2009. Exhibit 8 also at the bottom of</p> <p>13 the first page says Ethicon, Inc., 2009.</p> <p>14 MR. RESTAINO: Yes. And I wasn't really</p> <p>15 expecting on using them, and I downloaded those</p> <p>16 off of the net yesterday. So I'll limit my</p> <p>17 questions to that time period, is it 2009 and</p> <p>18 2000- --</p> <p>19 MR. RUMANEK: Well, this says 2009 on the</p> <p>20 front.</p> <p>21 BY MR. RESTAINO:</p> <p>22 Q Doctor, have you seen this -- this copy</p> <p>23 that -- the one that's dated 2009 before?</p> <p>24 A Yeah, I believe that was when it was.</p> <p>25 Q And just glancing through, and you can</p>	<p style="text-align: right;">Page 72</p> <p>1 still would want to know as a physician, wouldn't</p> <p>2 you?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 A I'd be looking at, you know, the general</p> <p>5 milieu of this procedure relative to the other</p> <p>6 things available in terms of incidence of events to</p> <p>7 give myself a -- you know, an overall idea of how</p> <p>8 this stacks up against what I may be using</p> <p>9 alternatively or so forth.</p> <p>10 Q Do you prescribe Cymbalta?</p> <p>11 A No. Probably have, but yeah.</p> <p>12 I know about the medication.</p> <p>13 Q Do you know that it's associated with</p> <p>14 hepatotoxicity?</p> <p>15 A Not specifically, no.</p> <p>16 Q Do you know what the incidence of</p> <p>17 hepatotoxicity is with Cymbalta?</p> <p>18 A Not off the top of my head.</p> <p>19 Q Do you know that if you look at the</p> <p>20 product for -- insert for Cymbalta, it will tell you</p> <p>21 the incidence of hepatotoxicity?</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 A It may, if you say so.</p> <p>24 Q When you -- do you look at product inserts</p> <p>25 for new drugs that you prescribe?</p>
<p style="text-align: right;">Page 71</p> <p>1 take as much time as you want, can you see listed</p> <p>2 anywhere what the incidence is of any adverse event?</p> <p>3 A No.</p> <p>4 Q And again, as we had discussed in our</p> <p>5 hypothetical about ovarian cancer in a drug, the</p> <p>6 incidence of an adverse event is important, isn't it</p> <p>7 not?</p> <p>8 MR. RUMANEK: Object to the form.</p> <p>9 A Depends on the circumstance.</p> <p>10 Q Well, let's use the circumstance of a mesh</p> <p>11 device. If someone came -- a rep came up to you and</p> <p>12 said, we would like for you to start using our</p> <p>13 new -- brand new device, I want to share with you</p> <p>14 that there was mesh erosion noted in the trials, and</p> <p>15 the mesh erosion was 95 percent, but they don't tell</p> <p>16 you that, that would be important to know, wouldn't</p> <p>17 it?</p> <p>18 A Well, the -- I would be more interested in</p> <p>19 the ramifications of it. I mean, you can have</p> <p>20 asymptomatic mesh erosions in 95 percent of people</p> <p>21 and they don't know it and don't have any issues</p> <p>22 with it. So it's all in the context of the</p> <p>23 incidence.</p> <p>24 Q And if they were severe mesh erosions, but</p> <p>25 the incidence wasn't listed, that is something you</p>	<p style="text-align: right;">Page 73</p> <p>1 A Not necessarily.</p> <p>2 Q In your general and supplemental reliance</p> <p>3 list, there's an article by Brubaker,</p> <p>4 B-r-u-b-a-k-e-r, L, et al., and it's titled Adverse</p> <p>5 Events Over Two Years After Retropubic Or</p> <p>6 Transobturator Midurethral Sling Surgery: Findings</p> <p>7 From The Trial Of Midurethral Slings (TOMUS) Study.</p> <p>8 Do you recall that -- that study?</p> <p>9 A Yes.</p> <p>10 MR. RESTAINO: And I'm going to go ahead</p> <p>11 and ask the court reporter to mark this as</p> <p>12 Number 9.</p> <p>13 (Exhibit 9 was marked for identification.)</p> <p>14 BY MR. RESTAINO:</p> <p>15 Q Now, Doctor, I didn't see where this study</p> <p>16 was included in your expert report. Did you utilize</p> <p>17 this study?</p> <p>18 A I don't recall if I had it. I'll have to</p> <p>19 look back, but I know I've looked at this study.</p> <p>20 Q And TOMUS, T-O-M-U-S, or TOMUS, however</p> <p>21 it's pronounced, this stands for The Trial of</p> <p>22 Midurethral Slings; is that correct?</p> <p>23 A Correct.</p> <p>24 Q And this is a randomized controlled trial,</p> <p>25 correct?</p>

<p style="text-align: right;">Page 74</p> <p>1 A I believe it was. Let's see. I thought I 2 saw randomized control someplace. Is there a place 3 specific on here? I'm looking under Materials and 4 Methods. 5 Q You know, unfortunately if you look at 6 reference number 4, which is what I -- I relied upon 7 and I pulled, but I did not publish -- print it out 8 for you. 9 A You talking about in this article? 10 Q Yes. Reference number 4 in this article, 11 which is on page 6 -- 12 A Okay. 13 Q -- it's by Albo, A-I-b-o, ME, The Trial Of 14 Midurethral Slings (TOMUS): Design And Methodology 15 as published there in the Journal of Applied 16 Research in 2008. I will represent to you, Doctor, 17 that this is a randomized controlled trial. 18 A Okay. Yeah, that was the original one 19 that this is based on, I believe. 20 Q Yes. 21 A Okay. 22 Q Yes. And as we discussed, the randomized 23 controlled trial is the gold standard of 24 epidemiological studies, correct? 25 A The highest level of evidence, correct.</p>	<p style="text-align: right;">Page 76</p> <p>1 Abstract and Objectives, the objective was to 2 "Describe surgical complications in 597 women over a 3 24-month period following randomization to 4 retropubic or transobturator midurethral sling." 5 Did I read that correctly? 6 A Correct. 7 Q So 597 here is over ten times the final 58 8 women that Nilsson, et al., looked at, correct? 9 A Right. 10 Q And the -- would it be okay with you if I 11 pronounced this study as the TOMUS study? 12 A Sure. 13 Q And in the TOMUS study, the patients were 14 randomized, were they not? 15 A Correct. 16 Q And, once again, randomization is to 17 minimize bias, which does not occur in the Nilsson 18 case series report, correct? 19 MR. RUMANNEK: Object to the form. 20 A It's a case series. 21 Q Without randomization? 22 A Without randomization, right. 23 Q Now, if you go to page 5, the very bottom 24 sentence going onto page 6, they write, "Two years 25 postoperatively, the retropubic procedures</p>
<p style="text-align: right;">Page 75</p> <p>1 Q All right. Now, if you turn to again that 2 same page, page 6, where the references were -- are, 3 are you there, sir? 4 A Page 6, yeah, uh-huh. 5 Q See under Acknowledgments, "This study was 6 supported by cooperative agreements from the 7 National Institute of Diabetes and Digestive and 8 Kidney Diseases," with all the various grant numbers 9 there. And then it's also, "Supported" -- it says, 10 "Supported was also provided by the National 11 Institute of Child Health and Human Development and 12 Office Of Research in Women's Health, the NIH." Do 13 you see where I read that from? 14 A Yes, I believe so, correct. 15 Q And then down below the authors, in 16 addition to the research funding, they list, as 17 required, whatever support they had received and 18 whatever consultations they had done in the past, 19 correct? 20 A Correct. 21 Q And none of these authors are paid by 22 Ethicon, correct? 23 A Let's see. Al- -- no, I don't see 24 Ethicon. 25 Q Now, if you look at the first page, the</p>	<p style="text-align: right;">Page 77</p> <p>1 demonstrate higher rates of voiding dysfunction and 2 UTI, while the transobturator procedures were 3 associated with higher rates of transient neurologic 4 symptoms." Did I read that correctly? 5 A Correct. 6 Q Now, transient means temporary, correct? 7 A Correct. 8 Q And UTI stands for urinary tract 9 infection? 10 A Correct. 11 Q Now, turn to page 7, there's a table, 12 Table 1. And on the left side, within the table 13 itself, they have Total Number of Patients and then 14 below that SAEs; do you see that, sir? 15 A Yes. 16 Q And SAEs, do you understand that to stand 17 for serious adverse events? 18 A Correct. 19 Q And the first one listed is bladder 20 perforation, correct? 21 A Correct. 22 Q And if you look under the columns to the 23 right under Retropubic, there's 15/15 and then 24 (5 percent), correct? -- 25 A Correct.</p>

<p style="text-align: right;">Page 78</p> <p>1 Q -- versus zero/zero under transobturator, 2 correct? 3 A Correct. 4 Q And if you look at the P-value of less 5 than .001, that would indicate statistical 6 significance; is that correct? 7 A Correct. 8 Q So 5 percent of the women in this study 9 sustained a bladder perforation versus zero that 10 received the obturator device; is that correct? 11 A Correct. 12 Q And, now, this 5 percent incidence of 13 bladder perforation with retropubic device is not 14 listed in the TVT-Retropubic or TVT-Exact IFU, is 15 it? 16 MR. RUMANEK: Object to the form. 17 A Well, bladder perforation is a common -- 18 not common, it's a known complication of any 19 incontinence procedure or any surgical incontinence 20 procedure regarding slings, Burches, pubovaginal 21 slings. Regardless of the type of procedure, it's a 22 known complication. 23 And specifically to this, it's not -- it 24 has no serious ramifications unless it's 25 unrecognized. You simply remove it and you're done.</p>	<p style="text-align: right;">Page 80</p> <p>1 you define serious. 2 Q And do you know how they define serious? 3 A No, I don't. 4 Q Going just by this table under Serious 5 Adverse Event, 5 percent of the women receiving the 6 retropubic device sustained this injury versus zero 7 with the transobturator; is that correct? 8 A Correct. 9 Q And so my only question is, this 5 percent 10 incidence rate is not listed in any instruction for 11 use manual that you've seen, correct? 12 A Correct. 13 Q And it's statistically significant? 14 A But I think it's -- 15 MR. RUMANEK: Object to the form. 16 A I think it's inconsequential clinically. 17 Q Okay. 18 A It wouldn't affect my use of the device or 19 not. 20 Q If you look further down between the 21 bolded black line, do you see Voiding Dysfunction 22 Requiring Surgery (and/or catheter use)? Do you see 23 where I am now? 24 A Correct. 25 Q And 3 percent receiving the retropubic</p>
<p style="text-align: right;">Page 79</p> <p>1 Q In this study of 597 women, how do you 2 know that there was no serious ramification of this 3 as listed serious adverse event? 4 A Well, because simply from clinical 5 experience when you have a bladder perforation, you 6 simply just replace the device and it's the same -- 7 it's the same clinical circumstance as when you 8 place the suprapubic catheter, it's a small 9 perforation of the bladder. You simply pull the 10 catheter out when you're done, and so there really 11 isn't any sequelae from that. 12 Q There are bladder perforations that have 13 required surgical intervention, are there not? 14 A Well, not to the size that you experience 15 with that -- with a retropubic sling in this 16 circumstance. It's smaller than a suprapubic 17 catheter, so you simply pull it out and you're done. 18 Q These authors listed the bladder 19 perforation under serious adverse event, did they 20 not? 21 A Correct, but the urinary tract infection 22 isn't necessarily a serious event either. I mean, 23 it's an event, but it's not a -- necessarily a 24 life-threatening circumstance, nor is a vaginal 25 epithelial perforation. So it all depends on how</p>	<p style="text-align: right;">Page 81</p> <p>1 device received -- sustained voiding dysfunction 2 requiring surgery and/or a catheter, once again, 3 versus zero with the transobturator; is that 4 correct? 5 A Correct. 6 Q And that incidence of 3 percent is not 7 listed in either IFU, correct? 8 MR. RUMANEK: Object to the form. 9 A It actually is favorable in the grand 10 scheme of incontinence procedures because this is 11 actually a lower number than other randomized 12 controlled trials looking at other incontinence 13 procedures. So, you know, again, taking it within 14 the context of a number versus the circumstance of 15 that number, I see it as being actually a -- an 16 advantage over other alternative surgeries. 17 Q It would not appear to be an advantage 18 over the transobturator in this case, in this 19 randomized controlled trial, would you agree? 20 A Correct. 21 Q And the finding is statistically 22 significant, correct? 23 MR. RUMANEK: Object to the form. 24 A Yes. 25 Q And so therefore it rules out the</p>

<p style="text-align: right;">Page 82</p> <p>1 likelihood of chance, correct?</p> <p>2 MR. RUMANEK: Object to the form.</p> <p>3 A Clinically speaking, it's -- it's an</p> <p>4 advantage over the other procedures.</p> <p>5 Q And then just below that two lines down</p> <p>6 or -- comes Other, and then Total Serious Adverse</p> <p>7 Events, the incidence was 15.4 percent versus</p> <p>8 8.7 percent, once again, statistically significant;</p> <p>9 is that correct?</p> <p>10 A Correct.</p> <p>11 Q And 15.4 percent, I'll represent to you,</p> <p>12 is -- is a 77 percent increased risk over the</p> <p>13 obturator device.</p> <p>14 MR. RUMANEK: Object to the form. Speaks</p> <p>15 for itself.</p> <p>16 MR. RESTAINO: Agreed, it speaks for</p> <p>17 itself.</p> <p>18 Q I'll let you know that I used my slide</p> <p>19 ruler and it came out with 77 percent. And, once</p> <p>20 again, this is a statistically significant finding,</p> <p>21 correct?</p> <p>22 A Right.</p> <p>23 Q And have you seen in any IFU or that --</p> <p>24 has any representative for Ethicon informed you that</p> <p>25 with their device, there was a 77 percent increased</p>	<p style="text-align: right;">Page 84</p> <p>1 A On my web page? No, I didn't know that.</p> <p>2 Q I'll go ahead and mark as Exhibit 10, and</p> <p>3 I will represent to you that I pulled this off the</p> <p>4 internet last night here.</p> <p>5 (Exhibit 10 was marked for</p> <p>6 identification.)</p> <p>7 A Let me see. I didn't know it was on</p> <p>8 there.</p> <p>9 Q Do you recognize this as being your</p> <p>10 website?</p> <p>11 A Yeah. I think this is a video, but it's</p> <p>12 not a video of the TVT-Secur. It's a retropubic</p> <p>13 sling.</p> <p>14 Q Well, on the top of the second page,</p> <p>15 you'll see the transobturator sling, brand names</p> <p>16 include, and then you have mini slings, brand names</p> <p>17 include TVT-Secur from Gynecare, but nowhere on your</p> <p>18 page is the TVT-Retropubic or the TVT-Exact, and</p> <p>19 I'm -- quite honestly, I was just confused as to</p> <p>20 why --</p> <p>21 A Oh, I don't even use those other products,</p> <p>22 so I don't -- you know, I'll -- I don't know when</p> <p>23 this was updated, but at no time recently because</p> <p>24 I've never used the Obtryx sling or the Monarch</p> <p>25 sling. I don't use the TVT-O. I did use the Uretex</p>
<p style="text-align: right;">Page 83</p> <p>1 risk of a serious adverse event based upon a</p> <p>2 randomized controlled TOMUS study?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 A I would say that this information's</p> <p>5 readily available to any physician who wants to find</p> <p>6 it. And so I think it's available, it's not</p> <p>7 hidden.</p> <p>8 Q It's available if one goes searching for</p> <p>9 it versus just picks up the IFU, which comes with</p> <p>10 the device, correct?</p> <p>11 MR. RUMANEK: Object to the form.</p> <p>12 A But you don't necessarily have the IFU</p> <p>13 before you're doing the -- you know, you're -- the</p> <p>14 IFU is in the box, okay. So if I'm in my office and</p> <p>15 I don't know something, it's a lot easier for me to</p> <p>16 go pull it up -- a report rather than go find the</p> <p>17 box. You know, in terms of readily available, I</p> <p>18 think it's just as readily available as any of this.</p> <p>19 Q Okay. Are you familiar with the TVT-Secur</p> <p>20 device, S-e-c-u-r?</p> <p>21 A I am, correct.</p> <p>22 Q And have you used that?</p> <p>23 A I think probably less than two times.</p> <p>24 Q Do you know it's listed as one of the TVT</p> <p>25 devices on your web page?</p>	<p style="text-align: right;">Page 85</p> <p>1 sling, but I haven't used the mini slings.</p> <p>2 Q I'm not sure if it printed here or not,</p> <p>3 but I'll -- yeah, the final page, it's copyright</p> <p>4 2017, so I was assuming this was a current,</p> <p>5 up-to-date version of your website.</p> <p>6 A Well, I'm sure it's been updated, but</p> <p>7 that's not what I use.</p> <p>8 Q Okay. Do you understand the Secur, if</p> <p>9 it's -- if I'm pronouncing that correctly, has been</p> <p>10 removed from the market?</p> <p>11 A I think I'm mentioning it over here as one</p> <p>12 of the many devices, but it says, "Not all slings</p> <p>13 are the same," and I have the TVT, "Find out</p> <p>14 specifically what your doctor means. Is it a</p> <p>15 retropubic, transobturator?" So I think I was</p> <p>16 listing these as a lot of different types of</p> <p>17 products out there, but I'm saying, you know, to me</p> <p>18 at least, specifically knowing what your physician's</p> <p>19 using and their experience with it is the crux of</p> <p>20 what I'm getting at, not all slings are the same.</p> <p>21 Q Do you understand that Secur was removed</p> <p>22 from the market?</p> <p>23 A Yes.</p> <p>24 Q Do you understand it was removed from the</p> <p>25 market because of an increase reporting of adverse</p>

<p style="text-align: right;">Page 86</p> <p>1 events to the FDA?</p> <p>2 MR. RUMANEK: Object to the form. That is</p> <p>3 inaccurate and mischaracterizes the evidence.</p> <p>4 Q I'll strike the question. What is your</p> <p>5 understanding as to why this occurred, the device</p> <p>6 was removed from the market?</p> <p>7 A I never even looked into it, so I don't</p> <p>8 know.</p> <p>9 Q Did you see news reports that it had been</p> <p>10 removed from the market?</p> <p>11 A No.</p> <p>12 Q Did you read anything in the newspaper</p> <p>13 about it being removed from the market?</p> <p>14 A I've come across the fact that it was</p> <p>15 removed. I don't specifically know. I wasn't using</p> <p>16 the product, so I wasn't, you know, following the</p> <p>17 chain of events with it.</p> <p>18 Q Inasmuch as you weren't using the product,</p> <p>19 do you have any personal or objective data to argue</p> <p>20 against it having been removed from the market?</p> <p>21 A No.</p> <p>22 Q Okay. When a device such as Secur is --</p> <p>23 Secur is removed from the market, do you believe</p> <p>24 it's inappropriate for television news or newspapers</p> <p>25 to carry such an announcement?</p>	<p style="text-align: right;">Page 88</p> <p>1 don't recall, probably less than 20, but, you know,</p> <p>2 various devices.</p> <p>3 MR. RUMANEK: And I just want to make sure</p> <p>4 it's clear, because I do think his question</p> <p>5 originally was TVT, specifically TVT slings.</p> <p>6 THE WITNESS: Oh.</p> <p>7 MR. RESTAINO: So let's ask him again.</p> <p>8 MR. RUMANEK: Yeah, because I want to make</p> <p>9 sure that's clear.</p> <p>10 BY MR. RESTAINO:</p> <p>11 Q Assuming no evidence were asked in the</p> <p>12 answer, but just for the record and make sure it's</p> <p>13 clear, have you removed a TVT-Retropubic or</p> <p>14 TVT-Exact sling?</p> <p>15 A Yes.</p> <p>16 Q Can you estimate for us how many?</p> <p>17 A I'd say probably less than five.</p> <p>18 Q Of the less than five that you estimate,</p> <p>19 did you have an opinion as a surgeon how many of the</p> <p>20 cases the reason for the surgery was the device</p> <p>21 itself?</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 A It's hard to know exactly because, you</p> <p>24 know, for the instance of pain, pain can be</p> <p>25 multifactorial. The device may happen to be there</p>
<p style="text-align: right;">Page 87</p> <p>1 MR. RUMANEK: Object to the form.</p> <p>2 A I believe it's freedom of speech, so it's</p> <p>3 public information.</p> <p>4 Q Now, have you -- are you familiar with the</p> <p>5 MAUDE, M-A-U-D-E, database?</p> <p>6 A Correct. Yes.</p> <p>7 Q And as compared to the FAERS or the FDA's</p> <p>8 drug adverse event database, do you understand that</p> <p>9 MAUDE has adverse events associated with medical</p> <p>10 devices?</p> <p>11 A Yes.</p> <p>12 Q Have you ever searched the MAUDE database</p> <p>13 to see if there are and, if so, how many adverse</p> <p>14 events are present regarding the TVT and TVT-Exact</p> <p>15 devices?</p> <p>16 A Not specifically.</p> <p>17 Q Forgive me if I'm misquoting you, but I</p> <p>18 think you estimated that you have taken out</p> <p>19 approximately 20 of the TVT or TVT-Exact mesh</p> <p>20 devices?</p> <p>21 A No, not specifically those. I mean, I've</p> <p>22 been --</p> <p>23 Q Okay.</p> <p>24 A You know, I was -- I think you asked how</p> <p>25 many slings I had removed or something, and I said I</p>	<p style="text-align: right;">Page 89</p> <p>1 too, so it's hard to make that exact A to B</p> <p>2 correlation. So a lot of times, you know, when</p> <p>3 you're removing something, it's a suspicion, a</p> <p>4 risk/benefit analysis.</p> <p>5 Q In any procedure where you've removed any</p> <p>6 mesh slings, so regardless of manufacturer, did you</p> <p>7 ever feel that the indication for the surgery was an</p> <p>8 adverse event of the mesh itself?</p> <p>9 MR. RUMANEK: Object to the form.</p> <p>10 A It's hard to know. It's really hard to</p> <p>11 know.</p> <p>12 Q Have you ever filed a report with the FDA</p> <p>13 for an adverse event associated with mesh?</p> <p>14 A I don't recall.</p> <p>15 Q Okay. Now, if we could turn to -- well, I</p> <p>16 think we're already there, page 3 of your expert</p> <p>17 report --</p> <p>18 A Okay.</p> <p>19 Q -- five lines up from the bottom, the</p> <p>20 sentence starts, "In the past several years"; do you</p> <p>21 see that, sir?</p> <p>22 A Yes.</p> <p>23 Q You write -- or in your report is written,</p> <p>24 "In the past several years, Plaintiffs' attorneys</p> <p>25 have embarked on a huge self-serving campaign to</p>

<p style="text-align: right;">Page 90</p> <p>1 actively encourage patients to enter into lawsuits 2 by advertising unsubstantiated and exaggerated 3 claims. This has created a wave of unfounded 4 patient fear and anxiety that I have personally seen 5 in my practice." Did I read that correctly? 6 A Yes. 7 Q Did you write that -- those sentences 8 yourself? 9 A Yeah. 10 Q Now, you write "a huge self-serving 11 campaign." How would you define huge? 12 A I can't really give you an exact 13 definition, but I think it's -- it's -- it's big and 14 I -- I mean, I think that, you know, over here, a 15 30 percent reduction in the number of patients 16 undergoing surgery for stress incontinence and 17 pelvic reconstructive surgery, I mean, that's a 18 bigger number than 1 percent. It's certainly not 19 100 percent, but it's a big number. 20 Q Do you have any objective evidence of how 21 much money is spent by lawyers on advertising? 22 A No, I don't. 23 Q Okay. 24 A No. 25 Q Now, a lawsuit, if it's successful, which</p>	<p style="text-align: right;">Page 92</p> <p>1 of money awarded in a judgment and the law firm 2 takes out their whatever percentage of it it is and 3 you subtract all the expenses, a lot of times the 4 plaintiffs will wind up walking away with less money 5 than went to the law firm and the expenses combined. 6 That's the way I'd see it. 7 Q That's a fair analysis if there's such a 8 case where the damages are X, but the expert 9 expenses are very high. 10 A Correct. Correct. 11 Q But I'll share with you that the client is 12 informed of that, if you want to proceed, this is 13 what it's going to cost, and then they make the 14 decision. Sometimes they're not looking for money, 15 but they're seeking justice. 16 A Yeah. No, I think in some cases, that's a 17 fair point, correct. 18 Q Now, as you sit here today, can you share 19 with us one advertisement where -- by lawyers 20 regarding mesh where there was false information 21 presented? 22 A It's how the information is presented. 23 It's not specific to types of surgeries. Like, for 24 example, using mesh for sacrocolpopexies, I think 25 the public interprets, you know, mesh, however it's</p>
<p style="text-align: right;">Page 91</p> <p>1 serves the law firm financially, but primarily 2 benefits the person who's been injured in the 3 lawsuit, wouldn't you agree? 4 MR. RUMANNEK: Object to the form. 5 A I disagree. 6 Q You disagree that it primarily benefits 7 the person who's been injured? 8 A I'd say it benefits more so the law firm. 9 I say that the plaintiff usually tends to get less 10 money in aggregate once you take out expenses and 11 all the other peripheral, you know, points. I think 12 that a lot of times the plaintiffs receive a very 13 small degree of the reward. 14 Q Do you know of law firms in the country 15 which have an internal standing order that the 16 plain- -- that the client never receives less than 17 50 percent of the recovery, therefore, receives 18 after expenses more than the law firm? 19 MR. RUMANNEK: Object to the form. 20 A No, I don't know anything about that. 21 Q Well, I'll represent to you that's a 22 standing in my law firm. We never make more money 23 than the patient -- or the client. 24 A Well, that's good. I mean, I -- it's been 25 my understanding that after you look at the amount</p>	<p style="text-align: right;">Page 93</p> <p>1 used, as being a red flag for a lawsuit. 2 And so, for example, in sacrocolpopexies, 3 mesh complications in general, and the research are 4 reported less often due to a lot of different 5 circumstances, but I think a lot of people see these 6 advertisements and apply what's advertised to all 7 these different types of surgeries. They just refer 8 to everything as a mesh procedure. 9 Q Are you speculating to that or do you have 10 objective evidence that that's what people -- 11 A Personal experience, correct. If I have a 12 patient who comes in having a sacrocolpopexy, on 13 numerous occasions patients have interpreted the 14 commercials to include the mesh used for a 15 sacrocolpopexy as being the mesh involved in 16 litigation for vaginal surgeries. And I think that 17 patients also interpret mesh involved with slings as 18 on the same par as the circumstances involved with 19 prolapse surgery. And I think the FDA has actually 20 made a distinction between those as well as various 21 organizations, AUGS, SUFU and so forth. 22 Q Now, that misunderstanding on behalf of 23 your patients, is that the fault of the attorney 24 advertisement or just misunderstanding on the part 25 of the patient?</p>

<p style="text-align: right;">Page 94</p> <p>1 A I think it's a combination of both. I 2 mean, I don't think -- I think that if you put a 3 broad statement out there about if you've had pelvic 4 mesh, you could be entitled to damages, people don't 5 know exactly what they've had done. I mean, I've 6 had patients who have come in who have pain and 7 they're, hey, I saw this commercial and I've got 8 this pain, and, you know, I want this mesh taken 9 out. And when I can find their old operative note, 10 you didn't have any mesh in your surgery. Well, why 11 do I have my pain? Oh, because pain occurs from 12 pelvic surgery.</p> <p>13 Q Is that the fault of the lawyer 14 advertising or the fault of the lack of education of 15 the patient?</p> <p>16 A Well, if you plant the seed, then hysteria 17 can grow. You know, if you say, hey, if you drink 18 bottled water and you got hiccups, give us a call, 19 you're going to have a lot of people calling 20 regardless of whether it's a causative point or not.</p> <p>21 Q Some of the advertisements state that -- 22 that the mesh devices have been removed from the 23 market, correct?</p> <p>24 A You know, I don't specifically know. You 25 know, I can't recall one specifically off the top of</p>	<p style="text-align: right;">Page 96</p> <p>1 Q Gynecare Prolift+M made by Ethicon has 2 been removed from the market, correct?</p> <p>3 A But you have to look at the circumstances 4 of some of these removals. I mean, it's not 5 necessarily a bad product, but, you know, sometimes 6 the litigation factors that play into it completely 7 make it a product not worth pursuing for a company.</p> <p>8 Q And what is the objective basis for that 9 statement?</p> <p>10 A I think just, logically speaking, if 11 there's no market for your product, you don't 12 produce the product anymore.</p> <p>13 Q But that's subjective, correct?</p> <p>14 A Correct.</p> <p>15 Q You don't have any evidence that --</p> <p>16 A I think logic -- I think logic would 17 dictate that. I mean --</p> <p>18 MR. RUMANNEK: Let him -- make sure -- let 19 him finish the question.</p> <p>20 THE WITNESS: I'm sorry.</p> <p>21 Q But you don't have any objective basis 22 that any of the devices I've mentioned so far have 23 been removed because of a decrease of sales 24 secondary to litigation, do you?</p> <p>25 MR. RUMANNEK: Object to the form.</p>
<p style="text-align: right;">Page 95</p> <p>1 my head, but if you say so, I'll believe it.</p> <p>2 Q Mesh devices have been removed from the 3 market, correct?</p> <p>4 A Yes.</p> <p>5 MR. RUMANNEK: Object to the form.</p> <p>6 Certain -- certain mesh devices have been 7 removed from the market. Neither of the 8 devices that we're here for today.</p> <p>9 Q Specifically, for example, as we 10 discussed, the ProtoGen device was removed from the 11 market, correct?</p> <p>12 A Correct.</p> <p>13 Q And you're familiar with ObTAPE, 14 ObT-A-P-E, which was made by Mentor Corporation?</p> <p>15 A Correct.</p> <p>16 Q Removed from the market, correct?</p> <p>17 A Correct.</p> <p>18 Q Avaulta Plus, A-v-a-u-l-t-a Plus, made by 19 C.R. Bard, Incorporated, has been removed from the 20 market, correct?</p> <p>21 A Correct.</p> <p>22 Q Gynecare ProLift made by the defendant in 23 this litigation, Ethicon, has been removed from the 24 market, correct?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 97</p> <p>1 A My assumption would be that the two go 2 hand in hand.</p> <p>3 Q Okay. The Gynecare TVT-Secur System, as 4 we discussed, has been removed from the market, 5 correct?</p> <p>6 A Correct.</p> <p>7 Q And that was made by Ethicon?</p> <p>8 A Correct.</p> <p>9 Q The Gynecare Prosima, P-r-o-s-i-m-a, 10 Pelvic Floor Repair System made by Ethicon has been 11 removed from the market, correct?</p> <p>12 A Correct.</p> <p>13 Q Now, I'll represent to you that each 14 withdrawal was followed by news stories, both on 15 television and in newspapers, which we can find on 16 Google.</p> <p>17 A Sure.</p> <p>18 Q How do you rule out the news stories on 19 television and/or in the print as being the source 20 of, as you write, "the wave of anxiety" you have 21 observed in your patients?</p> <p>22 A State that question again, please.</p> <p>23 Q How do you rule out your patients hearing 24 of these withdrawals on television and in the print, 25 or internet these days, and that being the source of</p>

<p style="text-align: right;">Page 98</p> <p>1 "the wave of anxiety," as you write, versus lawyer 2 advertising?</p> <p>3 A Because I think it's the advertising that 4 came first that led to -- you know, legal 5 advertising that came first that led to patient fear 6 over this that sort of spirals into lack of use of 7 the products that leads to news stories and so on 8 and so forth. So one begets the next.</p> <p>9 Q Are you familiar with cases where the FDA 10 has asked for a voluntary withdrawal of a device 11 based upon the number of adverse events it's 12 receiving, which then begets litigation, which then 13 begets news stories, and then potentially and 14 probably begets anxiety?</p> <p>15 MR. RUMANNEK: Are you -- with respect to 16 the devices that you've just mentioned or 17 generally speaking?</p> <p>18 MR. RESTAINO: The devices that have been 19 mentioned.</p> <p>20 MR. RUMANNEK: Okay. Object to the form. 21 Mischaracterizes the evidence.</p> <p>22 A You know, I don't know the exact 23 chronology of those individual devices, how the end 24 result came about.</p> <p>25 Q Have you conducted a formal study of your</p>	<p style="text-align: right;">Page 100</p> <p>1 A Yes.</p> <p>2 Q So I'll go ahead and ask the reporter to 3 mark the first one as Exhibit 11. 4 (Exhibit 11 was marked for 5 identification.)</p> <p>6 BY MR. RESTAINO:</p> <p>7 Q This article is titled The Role of 8 Midurethral Slings in 2014: Analysis of the Impact 9 of Litigation on Practice, published in Current 10 Bladder Dysfunction Report 2015, correct?</p> <p>11 A Yeah, yeah, yeah, okay. Yeah.</p> <p>12 Q And, now, again, you're relying upon this 13 paper as the basis for your opinion regarding 14 everything we just discussed, the lawyer 15 advertising, correct?</p> <p>16 MR. RUMANNEK: Object to the form.</p> <p>17 A No, unh-unh.</p> <p>18 Q What are you relying upon this article 19 for?</p> <p>20 A Well, I think I took some general 21 information out of here. I couldn't tell you 22 whether that 30 percent was specifically in here or 23 not. There was some other articles cited here, but, 24 you know, I'm also relying on my own observation in 25 my clinical practice.</p>
<p style="text-align: right;">Page 99</p> <p>1 patients that have presented with anxiety as a 2 result of the mesh they may or may not have in them 3 and the source of that anxiety, that being lawyer 4 advertising, TV news, internet, or newspapers?</p> <p>5 A No formal study, observation only.</p> <p>6 Q Now, you wrote, "Subsequently, there has 7 been a 30 percent reduction in the number of 8 patients undergoing stress incontinence and pelvic 9 reconstructive surgery." Do you recall writing 10 that? It's the final --</p> <p>11 A Yeah, that was --</p> <p>12 Q -- on page 3.</p> <p>13 A -- part of these -- from these articles 14 that I cited.</p> <p>15 Q And that's going to be my question, is, 16 has there been there a 30 percent reduction in your 17 private practice or was that 30 percent nationwide 18 or worldwide?</p> <p>19 A I'm just basing it on these articles, not 20 specific to my practice.</p> <p>21 Q And, now, these articles that you're 22 basing upon, they're at the page -- top of page 4?</p> <p>23 A Correct.</p> <p>24 Q And you've pulled these articles and 25 you've read these articles?</p>	<p style="text-align: right;">Page 101</p> <p>1 Q Have you charted the number of midurethral 2 sling surgeries that you've done in the last several 3 years and noted a 30 percent reduction in your 4 practice?</p> <p>5 A Well, I couldn't say I did the formal 6 numbers, but when I look at, you know, my practice 7 in general, the number of slings that I've done and 8 prolapse surgeries and so forth, it's definitely 9 decreased.</p> <p>10 Q And you attribute that to advertising, 11 lawyer advertising?</p> <p>12 A I attribute it to patient fear.</p> <p>13 Q But in your report, the only basis for 14 patient fear you list is lawyer advertising.</p> <p>15 A Well, I think, look, we don't live in a 16 bubble. I mean, people hear things on TV, they -- 17 you know, whether it's lawyer advertising, whether 18 it's TV shows, whether it's talking to friends of 19 theirs, whatever the case might be. I mean, the end 20 result has been a decreased number of procedures 21 being performed.</p> <p>22 Q Okay. I'll give you as much time that you 23 need to look at it, but does this article support 24 your opinion that there's been a 30 percent 25 reduction in number of midurethral sling surgeries?</p>

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<p>1 A I'll have to go through and see. I don't</p> <p>2 exactly recall where I came up with the number, but</p> <p>3 I can go through it and take a look.</p> <p>4 Q To perhaps save some time, if I could, if</p> <p>5 you would look on page 43 --</p> <p>6 A Okay.</p> <p>7 Q -- in the lower -- the left column lower</p> <p>8 paragraph, and take your time to read that, other</p> <p>9 than go through this paragraph, but you see they</p> <p>10 actually quote 34.1 percent --</p> <p>11 A 34.1.</p> <p>12 Q -- in there.</p> <p>13 A Okay.</p> <p>14 Q I just wanted to point that out to you,</p> <p>15 that is actually higher in this one particular</p> <p>16 article.</p> <p>17 A Okay.</p> <p>18 Q And again, that just might save you some</p> <p>19 time.</p> <p>20 A Sure. That's fine.</p> <p>21 Q Now, with this paragraph itself, let's</p> <p>22 take a look at it.</p> <p>23 Well, before we do that, turn to the next</p> <p>24 page, and right above the references, once again,</p> <p>25 there's the conflict of interest that journal</p>	<p>1 January 2007 and November of 2012. In 2011, the</p> <p>2 rate of MUS procedures decreased by 34.1 percent</p> <p>3 (Figure 1) [reference 59]. It is interesting to</p> <p>4 note that" -- "that there was no change in the use</p> <p>5 of slings after the 2008 FDA communication, which</p> <p>6 included MUS, yet there was a decrease following the</p> <p>7 2011 communication, which did not include MUS. The</p> <p>8 source of this shift may be multifactorial,</p> <p>9 including provider fear of litigation, lack of</p> <p>10 clarity around safety concerns associated with</p> <p>11 different uses of vaginal mesh, and patient fear</p> <p>12 from legal advertisements and media coverage that</p> <p>13 occurred after the 2011 warning." Did I read that</p> <p>14 directly?</p> <p>15 A Yes.</p> <p>16 Q So the authors here, including a defense</p> <p>17 expert, writes that there are four potential</p> <p>18 factors, and that patient fear from legal</p> <p>19 advertisement is but one of the four factors in the</p> <p>20 opinion of these writers, correct?</p> <p>21 MR. RUMANEK: Object to the form.</p> <p>22 A It's, yeah, one of many factors, correct.</p> <p>23 Q And, in fact, in looking at this paper in</p> <p>24 total, this -- they do not provide any original data</p> <p>25 in this article. It's not an original study, it's a</p>
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<p>1 articles -- journals are required today, correct?</p> <p>2 A Correct.</p> <p>3 Q Do you see that?</p> <p>4 MR. RUMANEK: Object to the form.</p> <p>5 Q And do you see that the final sentence of</p> <p>6 that, that J. Anger declares that she is an expert</p> <p>7 witness for Boston Scientific Corporation? Do you</p> <p>8 see that?</p> <p>9 A Yeah, it says investigator for FDA 522,</p> <p>10 Boston Scientific.</p> <p>11 Q And then the sentence after that.</p> <p>12 A Yeah. Okay. Correct.</p> <p>13 Q So one of the authors is actually an</p> <p>14 expert witness for the defense -- one of the</p> <p>15 defendants in the mesh litigation?</p> <p>16 A Correct.</p> <p>17 Q Now, returning to page 43 in this</p> <p>18 paragraph, they write, "Although providers report</p> <p>19 that their use of MUS" -- and, I'm sorry, for the</p> <p>20 record, that stands for midurethral sling?</p> <p>21 A Correct.</p> <p>22 Q -- "did not change in 2011, a study of</p> <p>23 utilization of MUS shows that, in fact, MUS use</p> <p>24 decreased significantly in 2011. The Humana</p> <p>25 Administrative Claims Database was analyzed between</p>	<p>1 review of materials already provided, would you</p> <p>2 agree?</p> <p>3 A I agree.</p> <p>4 Q Now, while your expert reports the anxiety</p> <p>5 from legal advertisement, your expert report and --</p> <p>6 which relies upon this article doesn't state that</p> <p>7 the anxiety is multifactorial and that it may, in</p> <p>8 fact, be due to provider fear of litigation, may be</p> <p>9 due to lack of clarity around safety concerns</p> <p>10 associated with different uses of vaginal mesh,</p> <p>11 from -- patient fear from legal advertisements and</p> <p>12 media coverage, the only one you've taken out of</p> <p>13 this is fear from legal advertisement; is that</p> <p>14 correct?</p> <p>15 MR. RUMANEK: Object to the form.</p> <p>16 Mischaracterizes the testimony.</p> <p>17 A So I answer that?</p> <p>18 Q Yeah, you can answer, sure.</p> <p>19 A Let me just re-read what I said over here.</p> <p>20 Well, it was my interpretation. I'm using</p> <p>21 this 30 percent number, but there were some other</p> <p>22 articles in here that we could pull and see if</p> <p>23 there's a specific -- I don't remember exactly where</p> <p>24 I got that percentage from, and it could be in one</p> <p>25 of these other articles over here.</p>

<p style="text-align: right;">Page 106</p> <p>1 Q Well, my question, sir, is not even the</p> <p>2 30 percent --</p> <p>3 A Right.</p> <p>4 Q -- but is the fact that one of the two</p> <p>5 papers that you referenced here in your paper cites</p> <p>6 that the source of the anxiety was multifactorial,</p> <p>7 they list four sources of that anxiety, only one of</p> <p>8 which was patient fear from legal advertisement,</p> <p>9 that's the only one that made it into your</p> <p>10 article -- in your expert report, correct?</p> <p>11 MR. RUMANEK: Object to the form.</p> <p>12 A That's the only one that I specifically</p> <p>13 mentioned.</p> <p>14 Q So let's look at the second citation here</p> <p>15 for this area, and that's Koo, K-o-o, and then the</p> <p>16 letter K, and Gromley, G-r-o-m-l-e-y, EA, titled</p> <p>17 Transvaginal Mesh In The Media Following The 2011</p> <p>18 U.S. Food And Drug Administration Public Health</p> <p>19 Notification Update. Followed in Neuro-urology and</p> <p>20 Urodynamics, February of 2017. We'll have this</p> <p>21 marked as 12?</p> <p>22 (Exhibit 12 was marked for</p> <p>23 identification.)</p> <p>24 BY MR. RESTAINO:</p> <p>25 Q Now, in the title, again, if I can address</p>	<p style="text-align: right;">Page 108</p> <p>1 Q And if you look at the audience on the</p> <p>2 first page, it's -- the first bullet point,</p> <p>3 "Healthcare providers who implant surgical mesh to</p> <p>4 repair pelvic organ prolapse and/or stress urinary</p> <p>5 incontinence," correct?</p> <p>6 A Correct.</p> <p>7 Q And that would be you?</p> <p>8 A Correct.</p> <p>9 Q And the second bullet point is,</p> <p>10 "Healthcare providers involved in the care of</p> <p>11 patients with surgical mesh implanted to repair</p> <p>12 pelvic organ prolapse and/or stress urinary</p> <p>13 incontinence." And I take that to mean other</p> <p>14 healthcare providers, for example, your staff or</p> <p>15 nurses, and do you interpret it the same way, not to</p> <p>16 exclude you?</p> <p>17 A Right. I mean --</p> <p>18 MR. RUMANEK: Object to the form.</p> <p>19 A -- healthcare providers, period.</p> <p>20 Q And then finally it's -- the last bullet</p> <p>21 point is, "Patients who are considering or have</p> <p>22 received a surgical mesh implant to repair pelvic</p> <p>23 organ prolapse and/or stress urinary incontinence,"</p> <p>24 correct?</p> <p>25 A Correct.</p>
<p style="text-align: right;">Page 107</p> <p>1 your attention there, it's the Transvaginal Mesh In</p> <p>2 The Media Following The 2011 U.S. Food And Drug</p> <p>3 Administration Public Health Notification Update,</p> <p>4 correct?</p> <p>5 A Correct.</p> <p>6 Q So before we get to the article, let's go</p> <p>7 ahead and mark as 13 the actual safety update from</p> <p>8 the FDA.</p> <p>9 (Exhibit 13 was marked for</p> <p>10 identification.)</p> <p>11 BY MR. RESTAINO:</p> <p>12 Q There you go, sir. Now, have you seen</p> <p>13 this safety update before?</p> <p>14 A Yes, I believe I have.</p> <p>15 Q And it's -- it is the 2011 U.S. FDA Public</p> <p>16 Health Notification Update. This was sent out by</p> <p>17 the FDA, correct?</p> <p>18 A Correct.</p> <p>19 Q And this was sent to "notify healthcare</p> <p>20 practitioners and patients about a serious public</p> <p>21 health concern," correct?</p> <p>22 A Correct.</p> <p>23 MR. RUMANEK: Object to the form.</p> <p>24 Q And it's dated July 13, 2011?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 109</p> <p>1 Q Now, if we turn to the second page of the</p> <p>2 update, you see the purpose they have listed right</p> <p>3 near the top of the page --</p> <p>4 A Uh-huh.</p> <p>5 Q -- is that, "On October 20th" -- "October</p> <p>6 20, 2008, the FDA issued a Public Health</p> <p>7 Notification and Additional Patient Information on</p> <p>8 serious complications associated with surgical mesh</p> <p>9 placed through the vagina (transvaginal placement)</p> <p>10 to treat POP and SUI," period. And you understand</p> <p>11 POP to stand for pelvic organ prolapse?</p> <p>12 A Correct.</p> <p>13 Q And SUI is stress urinary incontinence?</p> <p>14 A Correct.</p> <p>15 Q And today we're basically discussing SUI,</p> <p>16 correct?</p> <p>17 A Correct.</p> <p>18 Q And then paragraph -- two paragraphs down</p> <p>19 from that, they write, "The FDA is issuing this</p> <p>20 update to inform you that serious complications</p> <p>21 associated with surgical mesh for transvaginal</p> <p>22 repair of POP are not rare." Did I read that</p> <p>23 correctly?</p> <p>24 A Correct.</p> <p>25 Q And not rare is bolded by the FDA,</p>

<p style="text-align: right;">Page 110</p> <p>1 correct?</p> <p>2 A Correct.</p> <p>3 Q Now, do you recall receiving this on or</p> <p>4 about -- let me take that back.</p> <p>5 Do you recall seeing the 2008 initial</p> <p>6 safety update from the FDA?</p> <p>7 A Yes.</p> <p>8 Q And at that time, I don't have it in front</p> <p>9 of me, but again, it's not a memory test, but my</p> <p>10 understanding was they said that the conditions were</p> <p>11 considered to be rare --</p> <p>12 A Correct.</p> <p>13 Q -- would you agree?</p> <p>14 MR. RUMANEK: Object to the form.</p> <p>15 Q Now, in 2011 they're saying these</p> <p>16 complications are not rare --</p> <p>17 MR. RUMANEK: Object --</p> <p>18 Q -- correct?</p> <p>19 MR. RUMANEK: Object to the form.</p> <p>20 A Correct.</p> <p>21 Q Okay. Now, if we could turn back to the</p> <p>22 Koo article, which we -- I've marked as an exhibit</p> <p>23 just before this, so I think it's 12, the Koo</p> <p>24 article is the Transvaginal Mesh In The Media</p> <p>25 Following the 2011 U.S. Food And Drug Administration</p>	<p style="text-align: right;">Page 112</p> <p>1 within three years of the FDA announcement." Did I</p> <p>2 read that correctly?</p> <p>3 A Correct.</p> <p>4 Q Now, if you slide down a couple lines, you</p> <p>5 see Results, "90-5 articles met inclusion criteria.</p> <p>6 Mesh-related litigation was the most common headline</p> <p>7 subject (36 articles, 38 percent) and 54 percent of</p> <p>8 all articles referenced legal action. 57 articles</p> <p>9 (60 percent) cited at least one mesh-related</p> <p>10 complication."</p> <p>11 And then finally at the conclusions, they</p> <p>12 write, "Despite frequent media coverage of</p> <p>13 transvaginal mesh and its complications since 2001,</p> <p>14 very few news sources that cited the FDA warning</p> <p>15 distinguished between prolapse and incontinence.</p> <p>16 Given prevalent reporting of mesh-related</p> <p>17 litigation, the findings raised concern about how</p> <p>18 patients perceive safety and efficacy of</p> <p>19 transvaginal mesh, regardless of indication." Did I</p> <p>20 read that correctly?</p> <p>21 MR. RUMANEK: I'm just going to object.</p> <p>22 It speaks for itself. To the extent you</p> <p>23 misspoke or skipped a word or said something</p> <p>24 incorrectly, it speaks for itself.</p> <p>25 MR. RESTAINO: Agreed. English is my</p>
<p style="text-align: right;">Page 111</p> <p>1 Public Health Notification Update.</p> <p>2 Again, this is the second reference in</p> <p>3 your expert report following your writing that, "In</p> <p>4 the past several years, Plaintiffs' attorneys have</p> <p>5 embarked on a huge self-serving campaign to actively</p> <p>6 encourage patients to enter into lawsuits by</p> <p>7 advertising unsubstantiated and exaggerated claims.</p> <p>8 This has created a wave of unfounded patient fear</p> <p>9 and anxiety I have personally seen in my practice.</p> <p>10 Subsequently, there has been a 30 percent reduction</p> <p>11 in the number of patients undergoing stress</p> <p>12 incontinence and pelvic reconstructive surgery."</p> <p>13 And that is then followed on the next page by the</p> <p>14 two citations, correct?</p> <p>15 A Correct.</p> <p>16 Q Now, if we turn to the abstract of the Koo</p> <p>17 article, you see at the very top they write,</p> <p>18 "Prompted by patients' changing perceptions of</p> <p>19 transvaginal mesh, this study examines how mesh has</p> <p>20 been reported in the news following the 2011 U.S.</p> <p>21 Food and Drug Administration (FDA) updated</p> <p>22 notification about the use of mesh in the treatment</p> <p>23 of pelvic organ prolapse." Their methods, "Two</p> <p>24 national newspaper databases were queried for</p> <p>25 articles discussing transvaginal mesh published</p>	<p style="text-align: right;">Page 113</p> <p>1 second language.</p> <p>2 MR. RUMANEK: I do think you said 2001 at</p> <p>3 one point when the article says 2011, but --</p> <p>4 BY MR. RESTAINO:</p> <p>5 Q Now, Dr. Goldwasser, this article reviewed</p> <p>6 newspapers' articles.</p> <p>7 A Uh-huh.</p> <p>8 Q There's not a single description of lawyer</p> <p>9 advertising in this reference that you provide as</p> <p>10 support for your expert statement that lawyer</p> <p>11 advertising by self-serving lawyers has led to this</p> <p>12 wave of anxiety, correct?</p> <p>13 MR. RUMANEK: Object to form.</p> <p>14 A No, because it talks about mesh-related</p> <p>15 litigation.</p> <p>16 Q It talks about newspaper articles about</p> <p>17 the litigation, not lawyer advertising.</p> <p>18 MR. RUMANEK: Object to the form.</p> <p>19 A It's not specifically talking about lawyer</p> <p>20 advertising, but it encompasses advertising as part</p> <p>21 of that news reports.</p> <p>22 Q Sir, if we go back to the methods, they</p> <p>23 search two national newspaper databases.</p> <p>24 A Right.</p> <p>25 Q They pulled the articles about ongoing</p>

<p style="text-align: right;">Page 114</p> <p>1 litigation.</p> <p>2 A Right.</p> <p>3 Q I've read this very carefully, there's not</p> <p>4 a single mention in here of television legal</p> <p>5 advertising at all.</p> <p>6 A Well, I don't know that that is in those</p> <p>7 articles. I mean, mention -- I mean, yeah, it</p> <p>8 doesn't specifically say, you know, legal</p> <p>9 commercials here, but it's about the whole crux of</p> <p>10 litigation regarding this whole topic.</p> <p>11 Q If there's a lawsuit brought by someone --</p> <p>12 A Right.</p> <p>13 Q -- who has true injury from a device that</p> <p>14 has been removed from the market --</p> <p>15 A Right.</p> <p>16 Q -- and a newspaper reports on that</p> <p>17 litigation --</p> <p>18 A Uh-huh.</p> <p>19 Q -- that has nothing to do with lawyer</p> <p>20 advertising, would you agree?</p> <p>21 MR. RUMANEK: Object to the form.</p> <p>22 A Potentially, correct.</p> <p>23 Q But you're using this study as the basis</p> <p>24 for your opinion that lawyer advertising is what's</p> <p>25 creating this wave of anxiety, and this article does</p>	<p style="text-align: right;">Page 116</p> <p>1 Q Yeah.</p> <p>2 A Okay. I'm sort of losing train of what</p> <p>3 you just -- this specific article does not mention</p> <p>4 direct- -- directly mention legal advertising,</p> <p>5 correct.</p> <p>6 Q Okay. We can move on, then.</p> <p>7 Now, you have spent -- during the course</p> <p>8 of -- of -- you've dedicated a considerable amount</p> <p>9 of time to cadaver lab dissection during the course</p> <p>10 of product development as an instructor for</p> <p>11 physician training with Ethicon?</p> <p>12 MR. RUMANEK: Object to the form.</p> <p>13 A As part of my lab experience, correct.</p> <p>14 Q And did you charge Ethicon for your time</p> <p>15 or did Ethicon pay you for your time?</p> <p>16 MR. RUMANEK: Object to the form.</p> <p>17 A Well, part of that -- part of that lab</p> <p>18 stuff that I'm talking about had to do with</p> <p>19 development of a prolapse project, but -- and a lot</p> <p>20 of this has to do with, you know, during training</p> <p>21 sessions doing cadaveric dissections. So I guess</p> <p>22 when I was an instructor for Ethicon, it would be --</p> <p>23 it would fall into that. So some of this lab stuff</p> <p>24 that I'm referring to has to do with a lot of</p> <p>25 different projects.</p>
<p style="text-align: right;">Page 115</p> <p>1 not support that opinion.</p> <p>2 MR. RUMANEK: Well, hold up. He hasn't</p> <p>3 asked a question. That was a statement.</p> <p>4 Q Would you agree that this article does not</p> <p>5 support that legal advertising that's creating a</p> <p>6 wave of anxiety?</p> <p>7 MR. RUMANEK: Object to the form.</p> <p>8 A I would state that my interpretation of</p> <p>9 what I see clinically and take from these articles</p> <p>10 is that -- is that there's a lot of legal</p> <p>11 advertising that goes into the hysteria that has</p> <p>12 come about. I mean, yes, there are media reports,</p> <p>13 like you're mentioning over here, but my perception</p> <p>14 in talking with patients is that they -- all they</p> <p>15 talk about is commercials they see on TV.</p> <p>16 Q That may be, and I don't doubt the</p> <p>17 veracity of that statement, but you would agree that</p> <p>18 that's anecdotal evidence with you and your</p> <p>19 patients, and this published article does not</p> <p>20 support -- does not even mention legal</p> <p>21 advertising --</p> <p>22 MR. RUMANEK: Object to the form.</p> <p>23 Q -- does it?</p> <p>24 MR. RUMANEK: Asked and answered.</p> <p>25 A Answer again?</p>	<p style="text-align: right;">Page 117</p> <p>1 Q What's the purpose of cadaveric dissection</p> <p>2 and cadaveric study in -- with devices?</p> <p>3 MR. RUMANEK: Object to the form.</p> <p>4 A Learning anatomy.</p> <p>5 Q Same anatomy that was present on the</p> <p>6 videotapes?</p> <p>7 A Different anatomy, three dimensional.</p> <p>8 Q Now, you wrote that, "My extensive</p> <p>9 clinical training and cadaveric dissection</p> <p>10 experience led to my development and implantation of</p> <p>11 several devices and techniques for reconstructive</p> <p>12 pelvic surgery." Do you recall writing that, sir?</p> <p>13 A Yes.</p> <p>14 Q Have you patented any devices you've</p> <p>15 developed for reconstructive pelvic surgery?</p> <p>16 A Provisional, but not a full patent.</p> <p>17 Q Would that be the Exair, E-x-a-i-r?</p> <p>18 A Correct.</p> <p>19 Q Is that available in the United States?</p> <p>20 A No longer.</p> <p>21 Q When was it available?</p> <p>22 A I don't remember the exact time frame.</p> <p>23 Q Why is it no longer available?</p> <p>24 MR. RUMANEK: Object to form.</p> <p>25 A Product demand.</p>

<p style="text-align: right;">Page 118</p> <p>1 Q Did -- did it go through premarket 2 approval clinical testing? 3 MR. RUMANEK: Object to the form. 4 A I believe it was on one of the five 10K 5 market -- you know, like similar device project. 6 That's a prolapse procedure. 7 Q So it would fall under the predicate 8 device, the ProtoGen? 9 A If I remember -- 10 MR. RUMANEK: Object to the form. 11 Q But simply -- the only reason I'm 12 asking -- or trying to ask in a terrible way is, did 13 you have to conduct Phase 3 clinical trials with 14 this device? 15 A No. 16 Q Okay. Is -- I'll be honest with you, 17 it -- I'm sharing with you that when I searched 18 PubMed, I did not find any publications regarding 19 this. Has there been anything published about the 20 device in the peer-reviewed medical literature? 21 A No. 22 Q And then you also wrote that, based upon 23 your experience, quote, My extensive clinical 24 training and cadaver dissection experience led to my 25 development/implantation of several devices and</p>	<p style="text-align: right;">Page 120</p> <p>1 it. So is there a Wasserman technique for anything 2 within pelvic reconstructive surgery? 3 MR. RUMANEK: Goldwasser. 4 Q Goldwasser, I'm sorry. 5 MR. RUMANEK: Yeah, not Wasserman. 6 A No, there's not. 7 Q If any -- do you know if any of the 8 surgical techniques you developed as an instructor 9 for Ethicon is now generally accepted by the general 10 pelvic reconstructive surgery community? 11 MR. RUMANEK: Object to the form of the 12 question to the extent you're characterizing 13 develop within Ethicon -- I can't remember 14 exactly how you phrased it, but object to the 15 form of the question. 16 MR. RESTAINO: You know, yes, you're 17 right. Let me retract it. 18 Q Has any technique that you've developed at 19 any time for pelvic reconstructive surgery, is it 20 generally accepted now as accepted technique within 21 the urogynecological society? 22 A Yes. 23 Q And what technique is that? 24 A The Exair. 25 Q I'm sorry, is the Exair a device or a</p>
<p style="text-align: right;">Page 119</p> <p>1 techniques for reconstructive pelvic surgery. 2 Regarding the techniques themselves, have 3 any of the new or -- techniques that you've 4 developed been published and subjected to peer 5 review? 6 A They've been published but not 7 peer-reviewed. 8 Q Where have they been published? 9 A I think it was in some of these -- in the 10 CV, I think it was some presentation -- maybe it was 11 a presentation. I can't remember whether some of 12 these were published or not. I forgot exactly what 13 it was. 14 MR. RUMANEK: Your CV was 2. 15 A Somewhere in there I have it. 16 MR. RUMANEK: Here is your CV. 17 THE WITNESS: Oh. 18 A Let's see. So this was a presentation. I 19 don't see a publication here. For some reason I was 20 thinking there was a publication, but I must be 21 mistaken. 22 Q Has any of the techniques that you've 23 developed for reconstructive pelvic surgery -- you 24 know, sometimes you have the bi- -- the individual 25 themselves or others around them will put the name on</p>	<p style="text-align: right;">Page 121</p> <p>1 technique? 2 A It's a technique. 3 Q Oh, okay. 4 MR. RUMANEK: Let's go off the record for 5 just a second. 6 (Off-the-record discussion.) 7 BY MR. RESTAINO: 8 Q Doctor, it's my understanding that the 9 surgical technique that you described within your 10 expert report has to do with the Exair mesh device, 11 correct? 12 A Correct. 13 Q Now, you write, "A portion of my practice 14 involves re-operative management of recurrent 15 urinary incontinence and prolapse, as well as 16 treating and managing complications associated with 17 both mesh and non-mesh surgical procedures." Is 18 that a fair description of your practice? 19 A Yes. 20 Q Can you estimate what percentage of your 21 practice time involves re-operative management of 22 recurrent urinary incontinence secondary to previous 23 mesh surgical procedures? 24 MR. RUMANEK: Object to the form. 25 A I couldn't give you a specific number.</p>

<p style="text-align: right;">Page 122</p> <p>1 Q Okay. In surgery there may be situations</p> <p>2 where either because of training or desire a surgeon</p> <p>3 may elect to take on the more difficult cases that</p> <p>4 other surgeons either don't want to handle or</p> <p>5 haven't had the training to handle, does that make</p> <p>6 sense?</p> <p>7 A Yes.</p> <p>8 Q In this area are -- do you readily accept</p> <p>9 the more difficult cases?</p> <p>10 MR. RUMANEK: Object to the form.</p> <p>11 A It depends upon the circumstances.</p> <p>12 Q Okay. Can -- do you know when was the</p> <p>13 last time you removed a TVT-Retropubic mesh device?</p> <p>14 A Yes.</p> <p>15 Q When was that?</p> <p>16 A Probably about two months ago.</p> <p>17 Q And did you send that explanted or removed</p> <p>18 mesh device on for electro-microscopic examination</p> <p>19 of the mesh itself?</p> <p>20 A No.</p> <p>21 Q As you sit here today, do you have any</p> <p>22 objective evidence to show whether the mesh had</p> <p>23 degraded in vivo?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A No.</p>	<p style="text-align: right;">Page 124</p> <p>1 MR. RUMANEK: Object to the form.</p> <p>2 A Yes.</p> <p>3 Q And do you know how many times that</p> <p>4 prescription is filled?</p> <p>5 MR. RUMANEK: Object to the form.</p> <p>6 A I do not.</p> <p>7 Q Okay. As a physician and surgeon, do you</p> <p>8 have a knowledge of difference between acute</p> <p>9 postoperative pain from any surgery versus chronic</p> <p>10 pain?</p> <p>11 A Yeah, I think I have a pretty decent feel</p> <p>12 for the difference.</p> <p>13 Q And how would you describe in your patient</p> <p>14 population, and let's limit it with pain with mesh,</p> <p>15 chronic pain?</p> <p>16 MR. RUMANEK: Are you -- with respect to</p> <p>17 TVT or any mesh generally? I just want to make</p> <p>18 sure --</p> <p>19 MR. RESTAINO: Let's keep it to TVT, if we</p> <p>20 can.</p> <p>21 A How would I describe chronic pain?</p> <p>22 Q How would you differentiate chronic pain</p> <p>23 from acute postoperative pain, if there is any?</p> <p>24 A I would say that chronic pain is</p> <p>25 something -- in my mind is something that's been</p>
<p style="text-align: right;">Page 123</p> <p>1 Q And how about TVT-Exact, do you have</p> <p>2 knowledge as to when the last time you took one of</p> <p>3 those out?</p> <p>4 A It was an Exact that I was referring to.</p> <p>5 Q Oh, okay. Okay. So then I'll reverse it.</p> <p>6 Do you have knowledge as to when you took</p> <p>7 out a TVT-Retropubic device, just a TVT?</p> <p>8 A I don't recall.</p> <p>9 Q Okay.</p> <p>10 MR. RESTAINO: He answered a lot of these</p> <p>11 questions already.</p> <p>12 Q Now, as with any surgery, you would expect</p> <p>13 patients to whom you implant the TVT or the TV-Exact</p> <p>14 to experience some immediate postoperative pain,</p> <p>15 would you agree?</p> <p>16 MR. RUMANEK: Object to the form.</p> <p>17 A Not necessarily.</p> <p>18 Q Do most of your patients upon -- into whom</p> <p>19 you implant one or both of these devices or either</p> <p>20 of these devices experience some degree of</p> <p>21 postoperative pain?</p> <p>22 A I wouldn't say the majority do.</p> <p>23 Q Do you typically give patients when</p> <p>24 they're released from the office, clinic, or</p> <p>25 hospital a prescription for pain medication?</p>	<p style="text-align: right;">Page 125</p> <p>1 going on more than six months.</p> <p>2 Q Is there a specific test that you can --</p> <p>3 enables you to determine chronic pain or is it the</p> <p>4 period of time for which the pain exists?</p> <p>5 A Period of time.</p> <p>6 Q And would you agree that chronic pain may</p> <p>7 in and of itself be multifactorial?</p> <p>8 A Yes.</p> <p>9 Q And may one of those factors be a foreign</p> <p>10 body reaction?</p> <p>11 MR. RUMANEK: Object to the form.</p> <p>12 A It could be.</p> <p>13 Q And could one of the factors be scarring</p> <p>14 within the vagina?</p> <p>15 A Could be.</p> <p>16 Q If there is chronic pain that you feel as</p> <p>17 a clinician is a foreign body reaction, is that</p> <p>18 chronic pain more likely than not going to be</p> <p>19 obviated by removing the foreign body?</p> <p>20 MR. RUMANEK: Object to the form.</p> <p>21 A Well, it's difficult to say because there</p> <p>22 is no way to deduce the etiology of chronic pain.</p> <p>23 So you can hypothesize that it could be a foreign</p> <p>24 body reaction, but sometimes when you remove the</p> <p>25 foreign body, their pain doesn't change and so it's</p>

<p style="text-align: right;">Page 126</p> <p>1 hard to say.</p> <p>2 Q Okay. With any of the patients into whom</p> <p>3 you've implanted the TVT or TVT-Exact mesh, did any</p> <p>4 of them postoperatively develop urinary retention?</p> <p>5 A How do you define retention?</p> <p>6 Q The holding of urine longer than the</p> <p>7 normal physiological time which one would expect to</p> <p>8 urinate.</p> <p>9 A That's -- that's not -- can I go off the</p> <p>10 record and help you with the definition?</p> <p>11 Q Yeah, I would prefer using your</p> <p>12 definition.</p> <p>13 A Well, there is no -- there is no</p> <p>14 universally agreed-upon definition of retention, but</p> <p>15 retention refers to inability to empty the bladder</p> <p>16 as opposed to time period which one -- between which</p> <p>17 one voids. That's more frequency of urination. So</p> <p>18 you're asking about -- so you're asking about</p> <p>19 retention of urine as in incomplete emptying or are</p> <p>20 you talking about frequency of urination?</p> <p>21 Q Well, in my study of the germane</p> <p>22 literature, predominantly that that was within your</p> <p>23 expert report and your reliance lists, there are</p> <p>24 studies that report urinary retention and they don't</p> <p>25 go into any further description --</p>	<p style="text-align: right;">Page 128</p> <p>1 dysfunction but of no clinical consequence, so</p> <p>2 again, it's the trying to distinguish somebody who's</p> <p>3 got clinically significant problems versus just an</p> <p>4 observation.</p> <p>5 Q In any of the patients in which you have</p> <p>6 made a diagnosis of voiding dysfunction following</p> <p>7 any mesh procedure, did you report that to the FDA</p> <p>8 as an adverse event?</p> <p>9 A No.</p> <p>10 Q Following implantation of the TVT or</p> <p>11 TVT-Exact, have you had any patients who developed</p> <p>12 on overactive bladder, using your definition of an</p> <p>13 overactive bladder?</p> <p>14 A Well, any incontinence procedure has a</p> <p>15 certain number of, you know, reported events of</p> <p>16 developing overactive bladder.</p> <p>17 And by the same token, specifically with</p> <p>18 the midurethral slings, a lot of times</p> <p>19 pre-procedural overactive bladder will resolve in up</p> <p>20 to 50 percent of people. So it's a common finding.</p> <p>21 It's a known finding with any incontinence</p> <p>22 procedure.</p> <p>23 Q And whenever you've seen that and made a</p> <p>24 diagnosis, did you report that as an adverse event</p> <p>25 with the FDA?</p>
<p style="text-align: right;">Page 127</p> <p>1 A Right.</p> <p>2 Q -- within the table other than that. So</p> <p>3 my question was a general one. Have you ever had to</p> <p>4 make the diagnosis of urinary retention using your</p> <p>5 own diagnosis in any patient postoperatively</p> <p>6 following implantation of TVT or TVT-Exact?</p> <p>7 A I can't recall of any patient that has had</p> <p>8 an ongoing problem with urinary retention.</p> <p>9 Q Okay. I've also seen reports in the</p> <p>10 literature of voiding dysfunction, however that's</p> <p>11 defined, following TVT and TOT procedures. Have you</p> <p>12 seen reports about that?</p> <p>13 A Yes.</p> <p>14 Q Have you ever made the diagnosis of</p> <p>15 voiding dysfunction in any patient to whom you've</p> <p>16 implanted the TVT or the TVT-Exact?</p> <p>17 A I have seen patients with some voiding</p> <p>18 dysfunction with any incontinence procedure --</p> <p>19 Q Okay.</p> <p>20 A -- not specific to those two procedures.</p> <p>21 But, again, the definition of voiding dysfunction</p> <p>22 is -- is a moving target, you know.</p> <p>23 For example, some patients may say that</p> <p>24 they have to sit in a certain position to void, but</p> <p>25 they void just fine. So some may say that's voiding</p>	<p style="text-align: right;">Page 129</p> <p>1 A No, I have not seen it as being an adverse</p> <p>2 event.</p> <p>3 Q The overactive bladder can also be</p> <p>4 associated with the neurogenic bladder, correct?</p> <p>5 MR. RUMANEK: Object to the form.</p> <p>6 A No, they're actually two different</p> <p>7 diagnoses.</p> <p>8 Q Let me ask a better question. When a</p> <p>9 patient is diagnosed with a neurogenic bladder,</p> <p>10 that -- one form of a neurogenic bladder can be</p> <p>11 overactive, agreed?</p> <p>12 A Correct, but when you use the term</p> <p>13 "neurogenic," it means there's an underlying</p> <p>14 neurologic problem such as Multiple sclerosis or</p> <p>15 something along those lines.</p> <p>16 Q Or local nerve injury?</p> <p>17 A Yeah. Well, I mean, neurogenic in general</p> <p>18 has to do with a neurologic underlying basis for the</p> <p>19 problem, but it's usually thought of as being like a</p> <p>20 central nervous system disorder, not always, but, I</p> <p>21 mean, it's open for interpretation. I didn't mean</p> <p>22 to throw you a curve ball there.</p> <p>23 Q No, no, no, I just lost the name of it,</p> <p>24 but there's a major nerve, starts with a P.</p> <p>25 A The pudendal nerve.</p>

<p style="text-align: right;">Page 130</p> <p>1 Q Thank you, the pudendal nerve. An injury</p> <p>2 to the pudendal nerve during surgery can result in a</p> <p>3 neurogenic bladder, correct?</p> <p>4 A Pudendal nerve injuries aren't associated</p> <p>5 with retropubic slings or transobturator slings.</p> <p>6 Q No, I was just limiting that to general</p> <p>7 surgery, pelvic surgery.</p> <p>8 A Oh. Yeah, pelvic surgery, you can</p> <p>9 de-innervate the bladder, then cause either a long,</p> <p>10 you know, chronic or temporary voiding difficulties</p> <p>11 resulting in catheterization.</p> <p>12 Q Now, have you made that diagnosis in any</p> <p>13 patient into whom you've implanted a TVT or a</p> <p>14 TVT-Exact?</p> <p>15 A Not specifically that I can recall.</p> <p>16 Q Okay. On page, I think it's 13 of your</p> <p>17 expert report -- no, it's on page 12 of the expert</p> <p>18 report, you have a section on development of --</p> <p>19 well, let me -- before I go into this, do you need</p> <p>20 to take a break?</p> <p>21 A No.</p> <p>22 Q I'll just share with you that I'm on page</p> <p>23 30 of 397.</p> <p>24 A That's it?</p> <p>25 Q I'm on page 30 of 32. So if you can hold</p>	<p style="text-align: right;">Page 132</p> <p>1 A No.</p> <p>2 Q If we turn to page 28 of your report, and</p> <p>3 in the top paragraph, you -- you write a sentence</p> <p>4 about and then you again reference Nilsson,</p> <p>5 N-i-l-s-s-o-n, "The 17-year follow-up of</p> <p>6 tension-free vaginal tape procedure for female</p> <p>7 stress urinary incontinence," and that's the Nilsson</p> <p>8 we discussed earlier in the deposition, correct?</p> <p>9 A Correct.</p> <p>10 Q Then there's right below that a section on</p> <p>11 mechanical and laser cut. And did you write this</p> <p>12 paragraph -- did you write everything in your report</p> <p>13 yourself?</p> <p>14 A Yes.</p> <p>15 Q Okay. Now, you -- the second sentence in</p> <p>16 the first paragraph is, "The material in any</p> <p>17 particles would be the same prolene polypropylene</p> <p>18 material used in the mesh that, as discussed above,</p> <p>19 is a well-tolerated, biocompatible material." Did I</p> <p>20 read that correctly?</p> <p>21 A Correct.</p> <p>22 Q And, in fact, polypropylene is also used</p> <p>23 in many of the sutures available, correct?</p> <p>24 A Correct.</p> <p>25 Q Have you ever had a patient experience and</p>
<p style="text-align: right;">Page 131</p> <p>1 it, we're probably approaching that light at the end</p> <p>2 of the tunnel, okay, but you're welcome to take a</p> <p>3 break.</p> <p>4 A I'm fine.</p> <p>5 Q Development of the TVT, and you give a</p> <p>6 history here somewhat of the TVT development,</p> <p>7 correct?</p> <p>8 A Correct.</p> <p>9 Q Fair and balance, there's no mention in</p> <p>10 here of the number of trans- -- TVT meshes that have</p> <p>11 been taken off of the market, correct?</p> <p>12 MR. RUMANEK: Object to the form.</p> <p>13 Mischaracterizes the testimony and the report.</p> <p>14 A Correct, I did not specifically -- that</p> <p>15 wasn't my intent in that portion.</p> <p>16 Q Do you need to take a call?</p> <p>17 A No.</p> <p>18 MR. RUMANEK: I just want to state on the</p> <p>19 record, what's being discussed in this section</p> <p>20 is the development of the retropubic TVT, which</p> <p>21 has not been taken off the market. So I'm just</p> <p>22 not clear -- object to the form of your last</p> <p>23 question, unclear what you're referring to.</p> <p>24 Q Okay. To the best of your knowledge, has</p> <p>25 any TVT-Retropubic device been taken off the market?</p>	<p style="text-align: right;">Page 133</p> <p>1 have you made the diagnosis of what's -- may be</p> <p>2 called a spitting suture?</p> <p>3 A Yeah, I've seen it before.</p> <p>4 Q And can you describe for the record what</p> <p>5 is meant by someone spitting a suture. I mean, it's</p> <p>6 not literally coming out of their mouth, correct?</p> <p>7 A Correct. Typically it's referred to when,</p> <p>8 you know, maybe the sutures start popping out of the</p> <p>9 incision. Maybe it was either an incision on the</p> <p>10 surface of the skin and they start falling out, or</p> <p>11 maybe subcutaneous sutures starting to come out</p> <p>12 through the incision, so generally -- and, I mean,</p> <p>13 it's not a great scientific term, but it's been an</p> <p>14 observation.</p> <p>15 Q There's an inflammatory component</p> <p>16 associated with a spitting suture, isn't there?</p> <p>17 MR. RUMANEK: Object to the form.</p> <p>18 A Not necessarily. I mean --</p> <p>19 Q But there can be an inflammatory process</p> <p>20 which results in the pain, correct?</p> <p>21 MR. RUMANEK: Object to the form.</p> <p>22 A Well, you're referring to spitting of</p> <p>23 sutures or pain? You're --</p> <p>24 Q Referring to the pain that's secondary to</p> <p>25 the inflammation as the body forms a granuloma</p>

<p style="text-align: right;">Page 134</p> <p>1 around the polypropylene as it tries to extrude it 2 from the body, that is an immune reaction, correct? 3 MR. RUMANNEK: Object to the form. 4 A So let's go back. So you're talking about 5 a -- are you talking about polypropylene sutures 6 being spit out? I'm thinking more -- 7 Q Prolene. 8 A Typically when I've seen it, it's been 9 more of a VICRYL suture, a delayed absorbable 10 multifilament suture. That's when I typically see 11 spitting of sutures, per se. 12 Q Have you seen spitting of sutures with 13 polypropylene suture material? 14 A Not that I can really recall. 15 Q Have you studied about it? 16 A I haven't specifically embarked on that 17 study, no. 18 Q Okay. Would you agree that all foreign 19 material is recognized as foreign by the body which 20 leads to some degree of a foreign body reaction? 21 MR. RUMANNEK: Object to the form. 22 A It depends on the circumstance. I mean, 23 you can have an organ transplant and you suppress 24 the immune response to a foreign body. I mean, yes, 25 in general, foreign bodies are foreign bodies and so</p>	<p style="text-align: right;">Page 136</p> <p>1 they're all exposed to a foreign body and may or may 2 not have that foreign body response and don't 3 necessarily need pain medicine. 4 Q Do you agree that the laser-cut 5 methodology was specifically developed to eliminate 6 particle loss -- 7 MR. RUMANNEK: Object to -- 8 Q -- as seen in the mechanically cut? 9 MR. RUMANNEK: Object to form. 10 Q I'm sorry, I hesitated there. That was my 11 bad. 12 A Say it one more time. 13 Q Yeah. Would you agree that the laser-cut 14 methodology was specifically developed to eliminate 15 particle loss seen with mechanically cut mesh 16 material? 17 MR. RUMANNEK: Object to the form. 18 A I can't interpret exactly why Ethicon 19 developed the laser cut over the mechanical cut. I 20 mean, they're both available to some degree. I 21 don't know if they're -- if they're both available 22 right -- I don't -- I think the mechanical cut is 23 still available. But, you know, in reviewing the 24 internal documents, they have reasons cited as to 25 why they introduced two different types of mesh.</p>
<p style="text-align: right;">Page 135</p> <p>1 the body, you know, may in some circumstances have a 2 hyperacute immune response, may be a very subtle 3 immune response. I mean, it varies from person to 4 person and probably situational. 5 Q And that same response which can vary 6 will -- can manifest itself, can it not, as pain in 7 the patient, which can vary from patient to 8 patient -- 9 MR. RUMANNEK: Object to the form. 10 Q -- would you agree? 11 A If you go by the premise that a foreign 12 body reaction is always going to be painful, it may 13 not necessarily cause pain, but it's possible. 14 Q So if there was particle loss because of a 15 mechanically cut mesh, one would expect that each 16 particle being a foreign body would elicit a foreign 17 body response, whatever that may entail, including 18 white blood cells and form granuloma formation 19 around the particle, do you agree? 20 MR. RUMANNEK: Object to the form. 21 A You could have a foreign body response, 22 but, clinically speaking, I mean, the vast majority 23 of patients, like we discussed, you know, when they 24 have slings, they typically don't need any pain 25 medication postoperatively, and so theoretically</p>	<p style="text-align: right;">Page 137</p> <p>1 Q Have you seen any e-mails that 2 specifically discuss why the laser-cut methodology 3 was developed? 4 A Yes. 5 Q And do they specifically mention particle 6 loss from the mechanically cut mesh? 7 MR. RUMANNEK: Object to the form. 8 A Well, they specifically mention it in 9 terms of context of the company has been very open, 10 in looking through their documents that -- and 11 looking into reports from physicians. And so some 12 of the e-mails that I read mention some of the 13 physicians who are big users of the product 14 mentioning that in some circumstances, they may see 15 small particles of the mesh coming off, you know. 16 And a lot of the documents discuss that saying they 17 really don't find any clinical relevance to it, but 18 it's a perception. And in a lot of cases, 19 perception goes a long way. 20 And so I think the whole impetus to come 21 up with a different type of mesh manufacturing 22 process was to get rid of that perception, and so I 23 think that's why they looked at two different -- 24 again, my interpretation of their documents is why 25 they came up with two different types of ways to</p>

<p style="text-align: right;">Page 138</p> <p>1 produce the sling.</p> <p>2 MR. RESTAINO: I don't have any further</p> <p>3 questions.</p> <p>4 THE WITNESS: Good answer. I took all</p> <p>5 your questions.</p> <p>6 MR. RESTAINO: You took away three</p> <p>7 documents.</p> <p>8 THE WITNESS: Oh, really? Man.</p> <p>9 MR. RUMANEK: Let me take a five-minute</p> <p>10 break and I'll have a few.</p> <p>11 (Recess from 12:14 p.m. to 12:29 p.m.)</p> <p>12 CROSS EXAMINATION</p> <p>13 BY MR. RUMANEK:</p> <p>14 Q All right. All right. Dr. Goldwasser,</p> <p>15 I've just got -- and it won't be nearly as long, but</p> <p>16 I have some questions for you as well.</p> <p>17 Let's take a look at your expert report,</p> <p>18 which is marked as Exhibit 5.</p> <p>19 A Okay.</p> <p>20 Q And you note in the first paragraph of</p> <p>21 your expert report that the opinions that are set</p> <p>22 forth in your report are held to a reasonable degree</p> <p>23 of medical certainty; do you see that?</p> <p>24 A Yes.</p> <p>25 Q Do you recall being asked questions by</p>	<p style="text-align: right;">Page 140</p> <p>1 certain degree?</p> <p>2 A Yes.</p> <p>3 Q You're not a practicing pathologist, are</p> <p>4 you?</p> <p>5 A Correct, no.</p> <p>6 Q But you have understanding of pathology as</p> <p>7 it relates to the -- your practice and the practice</p> <p>8 of urogynecology?</p> <p>9 A Yes.</p> <p>10 Q And to the extent that any of the opinions</p> <p>11 that you've given in this report relate to pathology</p> <p>12 as it relates to mesh or urogynecology, do you</p> <p>13 believe that you have experience and expertise to</p> <p>14 give those opinions to a reasonable degree of</p> <p>15 medical certainty?</p> <p>16 A Yes.</p> <p>17 Q And the same would be true for the other</p> <p>18 areas of medicine that Opposing Counsel asked you</p> <p>19 about?</p> <p>20 A Yes.</p> <p>21 Q Counsel marked your reliance list and your</p> <p>22 supplemental reliance list as Exhibits 3 and</p> <p>23 Exhibits 4. And do you recall being asked questions</p> <p>24 about the information that's included in Exhibits 3</p> <p>25 and 4?</p>
<p style="text-align: right;">Page 139</p> <p>1 Opposing Counsel as to whether you considered</p> <p>2 yourself to be an expert in various fields? I can't</p> <p>3 remember what all of them were, but pathology,</p> <p>4 material science, I think maternal --</p> <p>5 A Maternal fetal medicine.</p> <p>6 Q -- maternal fetal medicine. Do you recall</p> <p>7 those questions?</p> <p>8 A Yes.</p> <p>9 Q To the extent that any of those fields of</p> <p>10 study could be characterized to touch on the</p> <p>11 opinions that you've given in your report, do you</p> <p>12 believe as you sit here today that you have</p> <p>13 sufficient expertise to give the opinions that</p> <p>14 you've set forth in your report to a reasonable</p> <p>15 degree of medical certainty?</p> <p>16 A Yes.</p> <p>17 MR. RESTAINO: Objection.</p> <p>18 Q And do you have expertise in the areas of</p> <p>19 practice necessary to give your opinions set forth</p> <p>20 in your report?</p> <p>21 A Yes.</p> <p>22 Q And so to the extent that any of the</p> <p>23 opinions -- let me strike that.</p> <p>24 Do you have knowledge as a physician, as a</p> <p>25 urogynecologist, of certain -- of pathology to a</p>	<p style="text-align: right;">Page 141</p> <p>1 A Yes.</p> <p>2 Q When you were initially asked to serve as</p> <p>3 an expert witness, were you provided a large body of</p> <p>4 medical literature that you could consider in</p> <p>5 forming your opinions?</p> <p>6 A Yes.</p> <p>7 Q And was that literature provided to you by</p> <p>8 counsel for Ethicon?</p> <p>9 A Correct.</p> <p>10 Q Did counsel for Ethicon tell you which</p> <p>11 articles you had to review and which ones you</p> <p>12 shouldn't review?</p> <p>13 A Not at all.</p> <p>14 Q Were you also provided internal company</p> <p>15 documents, documents from Ethicon, e-mails and</p> <p>16 things of that nature?</p> <p>17 A Yes.</p> <p>18 Q Did anybody from Ethicon tell you which</p> <p>19 documents you had to review and which ones -- that</p> <p>20 you shouldn't review any of them?</p> <p>21 A No.</p> <p>22 Q Okay. And were you also provided with</p> <p>23 deposition transcripts and videos and IFUs, other</p> <p>24 materials that are reflected on your materials list</p> <p>25 from counsel for Ethicon?</p>

<p style="text-align: right;">Page 142</p> <p>1 A Yes.</p> <p>2 Q And did anyone from Ethicon or any counsel</p> <p>3 for Ethicon tell you that you had to review certain</p> <p>4 materials or that you shouldn't review any of those</p> <p>5 materials?</p> <p>6 A No.</p> <p>7 Q Okay. Is it fair to say that those</p> <p>8 materials were given to you to consider as you felt</p> <p>9 it was necessary in forming your opinions?</p> <p>10 A Yes.</p> <p>11 Q Dr. Goldwasser, we're here today to be --</p> <p>12 so that you could give your deposition with respect</p> <p>13 to your TVT and TVT-Exact general report, correct?</p> <p>14 A Correct.</p> <p>15 Q In the course of serving as an expert</p> <p>16 witness in this litigation, did you also put</p> <p>17 together a Prolift general report?</p> <p>18 A Yes.</p> <p>19 Q And have you reviewed expert reports of</p> <p>20 plaintiffs' experts in the course of serving as an</p> <p>21 expert for Ethicon?</p> <p>22 A Yes.</p> <p>23 Q And have you also reviewed individual</p> <p>24 cases of plaintiffs who have brought claims against</p> <p>25 Ethicon related to either the Prolift, the TVT, or</p>	<p style="text-align: right;">Page 144</p> <p>1 that were cited in your general report. I don't</p> <p>2 know the exact number, maybe four or five articles.</p> <p>3 Do you recall getting questions about some of the</p> <p>4 articles?</p> <p>5 A Yes.</p> <p>6 Q And he didn't ask you about all the</p> <p>7 articles that were cited in your report, correct?</p> <p>8 A Correct.</p> <p>9 Q So one of the articles that he asked you</p> <p>10 about was the Nilsson 17-year study, correct?</p> <p>11 A Correct.</p> <p>12 Q Is that the only article that you're</p> <p>13 relying on to support your opinions that the TVT and</p> <p>14 TVT-Exact are safe and effective?</p> <p>15 A No.</p> <p>16 Q In your opinion, are the -- are the</p> <p>17 opinions that you've set forth in your report --</p> <p>18 strike that.</p> <p>19 You were asked questions about different</p> <p>20 study types, randomized clinical trials, cohort</p> <p>21 studies, case series, things of that nature, do you</p> <p>22 recall Counsel asking you those questions?</p> <p>23 A Yes.</p> <p>24 Q With respect to the literature discussing</p> <p>25 midurethral slings, are there also Cochrane Reviews</p>
<p style="text-align: right;">Page 143</p> <p>1 the TVT-Exact?</p> <p>2 A Yes.</p> <p>3 Q In the course of drafting your Prolift</p> <p>4 report, did you review medical literature?</p> <p>5 A Yes.</p> <p>6 MR. RESTAINO: Objection.</p> <p>7 Q And did you also review company documents</p> <p>8 that were provided to you by Ethicon when you were</p> <p>9 putting together your Prolift general report?</p> <p>10 MR. RESTAINO: Objection.</p> <p>11 A Yes.</p> <p>12 Q And some of the information that's</p> <p>13 contained in your Prolift general report was -- I</p> <p>14 don't know if it's word for word, but was similar</p> <p>15 information -- some of the information contained in</p> <p>16 the Prolift report also applicable to the opinions</p> <p>17 that you've given in your TVT and TVT-Exact general</p> <p>18 report?</p> <p>19 A Yes.</p> <p>20 Q And so is it fair to say that some of the</p> <p>21 documents and literature that you reviewed in</p> <p>22 putting together your Prolift general report also</p> <p>23 applied to your TVT and TVT-Exact general report?</p> <p>24 A Yes.</p> <p>25 Q Okay. Counsel showed you some articles</p>	<p style="text-align: right;">Page 145</p> <p>1 and meta-analysis?</p> <p>2 A Yes.</p> <p>3 Q What is -- can you explain, what is a</p> <p>4 Cochrane Review?</p> <p>5 A A Cochrane Review, it's a database with,</p> <p>6 you know, a lot of different data, different</p> <p>7 subjects. In this case, they'll -- you know, the</p> <p>8 author for the study may go through and do a</p> <p>9 meta-analysis looking at the statistics in that</p> <p>10 database, or possibly a systematic review would be</p> <p>11 another type of paper that might be published</p> <p>12 looking at just the overall findings from the</p> <p>13 database.</p> <p>14 Q And when you -- when you're talking about</p> <p>15 the systematic review or the database, is it fair to</p> <p>16 say that there are a number of randomized clinical</p> <p>17 trials that evaluated midurethral slings?</p> <p>18 A Yes.</p> <p>19 Q And are these meta-analysis, is it fair to</p> <p>20 say that those look at various randomized clinical</p> <p>21 trials and kind of pull the data from various</p> <p>22 randomized clinical trials?</p> <p>23 A Correct.</p> <p>24 Q And there was some question of levels of</p> <p>25 evidence and a randomized controlled trial being,</p>

<p style="text-align: right;">Page 146</p> <p>1 you know, at the top or gold standard. Would a</p> <p>2 meta-analysis or a Cochrane Review, which looks at</p> <p>3 data from multiple randomized controlled trials,</p> <p>4 would that be even higher than one individual</p> <p>5 randomized clinical trial?</p> <p>6 MR. RESTAINO: Objection.</p> <p>7 A Yes.</p> <p>8 Q Can you explain -- since there was an</p> <p>9 objection, let me just clarify that.</p> <p>10 In terms of ranking studies, where does a</p> <p>11 Cochrane Review or a large meta-analysis or</p> <p>12 systematic analysis, where does that rank in terms</p> <p>13 of levels of evidence?</p> <p>14 A It would be the highest level of evidence.</p> <p>15 Q Even higher than one individual randomized</p> <p>16 clinical trial, controlled trial?</p> <p>17 A Correct.</p> <p>18 Q Do you have Exhibit 9 -- can you pull</p> <p>19 Exhibit 9 in front of you, which was the TOMUS</p> <p>20 study? Do you have a copy of that?</p> <p>21 A Yeah.</p> <p>22 Q And this study was a comparison of adverse</p> <p>23 events with respect to retropubic and transobturator</p> <p>24 midurethral slings, correct?</p> <p>25 A Correct.</p>	<p style="text-align: right;">Page 148</p> <p>1 data related to the retropubic and transobturator,</p> <p>2 the results from this study for the retropubic and</p> <p>3 transobturator, it doesn't have data for non-mesh</p> <p>4 procedures, does it?</p> <p>5 A Correct.</p> <p>6 Q Okay. And are there studies and</p> <p>7 meta-analysis that look at the efficacy and</p> <p>8 complications associated with not only midurethral</p> <p>9 slings but also non-mesh procedures?</p> <p>10 A Yes.</p> <p>11 Q Okay. And have you set out data comparing</p> <p>12 those things in your report?</p> <p>13 A Yes.</p> <p>14 Q Okay. Counsel asked you if you look at</p> <p>15 Table 1 for voiding dysfunction, for example, that</p> <p>16 there was a 3 percent -- in this TOMUS study, a</p> <p>17 3 percent voiding dysfunction requiring surgery in</p> <p>18 the retropubic arm, correct?</p> <p>19 A Correct, 3 percent.</p> <p>20 Q And zero in the transobturator arm?</p> <p>21 A Correct.</p> <p>22 Q And Counsel asked you whether that</p> <p>23 specific percentage was reflected in the IFU, do you</p> <p>24 recall those questions?</p> <p>25 A Correct.</p>
<p style="text-align: right;">Page 147</p> <p>1 Q So on one arm was a retropubic</p> <p>2 polypropylene midurethral sling, the other arm was a</p> <p>3 transobturator polypropylene sling, correct?</p> <p>4 A Correct.</p> <p>5 Q If you will flip over to page 5 of the</p> <p>6 study, about halfway down, do you see where it</p> <p>7 references a sister trial comparing Burch and</p> <p>8 pubovaginal slings?</p> <p>9 A Correct.</p> <p>10 Q And is that trial cited in your expert</p> <p>11 report?</p> <p>12 A Yes, I believe it is. Yeah.</p> <p>13 Q And was that a trial that looked -- that</p> <p>14 looked at the Burch procedure and pubovaginal</p> <p>15 slings, the success -- the efficacy and</p> <p>16 complications associated with those two procedures?</p> <p>17 A Yes.</p> <p>18 Q Okay. And does this TOMUS study note that</p> <p>19 comparing the Burch and pubovaginal slings,</p> <p>20 concomitant surgery was associated with</p> <p>21 significantly higher rates of both adverse events</p> <p>22 and serious adverse events? Do you see that?</p> <p>23 A Correct.</p> <p>24 Q And so when you flip over to page 7, which</p> <p>25 is the table that Counsel asked you about, that has</p>	<p style="text-align: right;">Page 149</p> <p>1 Q Dr. Goldwasser, do you agree with me that</p> <p>2 if we looked at various studies, that 3 percent</p> <p>3 number in the retropubic arm, if you looked at a</p> <p>4 different study, would that number potentially</p> <p>5 change?</p> <p>6 MR. RESTAINO: Objection.</p> <p>7 A Yes.</p> <p>8 Q Are there some studies where voiding</p> <p>9 dysfunction could be higher than 3 percent?</p> <p>10 A Yes.</p> <p>11 Q And there's some studies perhaps where</p> <p>12 that number would be lower for retropubic?</p> <p>13 A Correct.</p> <p>14 Q Are you aware of literature that would</p> <p>15 suggest that transobturator slings can have a risk</p> <p>16 of voiding dysfunction?</p> <p>17 A Yes.</p> <p>18 Q Counsel asked you some questions about</p> <p>19 whether or not the incidence of adverse event</p> <p>20 reports were included in the IFUs for the TVT and</p> <p>21 TVT-Exact, do you recall those questions?</p> <p>22 A Yes.</p> <p>23 Q What -- can you explain, what is an</p> <p>24 adverse event report?</p> <p>25 A That's any event that's other than what</p>

<p style="text-align: right;">Page 150</p> <p>1 would anticipate the goal of the procedure.</p> <p>2 Q Okay. And if -- is there any restriction</p> <p>3 on who can report an adverse event to a</p> <p>4 pharmaceutical company or to the FDA?</p> <p>5 A No.</p> <p>6 Q Would it be possible for a patient to call</p> <p>7 the FDA and report an adverse event that they</p> <p>8 contend to be associated with any medical device?</p> <p>9 A Yes.</p> <p>10 Q And so if -- if I had a knee implant and</p> <p>11 my fingernail fell off, could I call and report that</p> <p>12 to the FDA that after my knee implant, my fingernail</p> <p>13 fell off?</p> <p>14 A Yes.</p> <p>15 Q Would that be something -- in terms of</p> <p>16 levels of evidence, where does an adverse event</p> <p>17 report fall in levels of evidence?</p> <p>18 A The lowest, around the idea of a case</p> <p>19 report per se or an incident report.</p> <p>20 Q And a case report to the extent it's --</p> <p>21 strike that.</p> <p>22 In terms of midurethral slings, as a</p> <p>23 physician, what data do you look to -- strike that.</p> <p>24 What's more significant in terms of levels</p> <p>25 of evidence between incidence of adverse events and</p>	<p style="text-align: right;">Page 152</p> <p>1 evidence perspective, what is the significance of</p> <p>2 adverse event reports?</p> <p>3 A Well, it depends on the circumstance. I</p> <p>4 mean, there's a lot of just false alarms constantly</p> <p>5 going off.</p> <p>6 Q And let me say this, if there exists</p> <p>7 systematic reviews, meta-analysis, and Cochrane</p> <p>8 Reviews, what would be the -- how would you as a</p> <p>9 physician use an adverse event report compared to</p> <p>10 that data?</p> <p>11 A As a very low level of evidence.</p> <p>12 Q Okay. Counsel asked you some questions</p> <p>13 about the IFU for TVT and TVT-Exact, do you recall</p> <p>14 that?</p> <p>15 A Yes.</p> <p>16 Q Prior to the TVT midurethral sling coming</p> <p>17 onto the market, were there non-mesh procedures that</p> <p>18 doctors were performing to treat stress urinary</p> <p>19 incontinence?</p> <p>20 A Yes.</p> <p>21 Q Let me strike -- let me ask that a</p> <p>22 different way. Before any mesh surgeries were</p> <p>23 performed to treat stress urinary incontinence, were</p> <p>24 doctors treating stress urinary incontinence</p> <p>25 surgically using non-mesh procedures?</p>
<p style="text-align: right;">Page 151</p> <p>1 systematic reviews of randomized controlled trials?</p> <p>2 A Definitely the randomized control</p> <p>3 systematic reviews are a higher level of evidence.</p> <p>4 Q And are those available to physicians in</p> <p>5 the medical literature?</p> <p>6 A Yes.</p> <p>7 Q And are those cited in your report?</p> <p>8 A Yes.</p> <p>9 Q Counsel asked you a question -- let me</p> <p>10 strike that.</p> <p>11 Are adverse event reports, do you expect</p> <p>12 that a manufacturer of medical devices would alert</p> <p>13 you every time they had an adverse event report</p> <p>14 related to their product?</p> <p>15 MR. RESTAINO: Objection.</p> <p>16 A No.</p> <p>17 Q Is that something that you would want in</p> <p>18 your practice?</p> <p>19 A No.</p> <p>20 Q Can you explain why that is.</p> <p>21 A Because you would be pretty much inundated</p> <p>22 with reports all day long from every single thing</p> <p>23 out there. And it would be tough to just practice</p> <p>24 medicine, you'd be listening to reports all day.</p> <p>25 Q And what would be the -- from a medical</p>	<p style="text-align: right;">Page 153</p> <p>1 A Yes.</p> <p>2 Q Okay. And if we look at your expert</p> <p>3 report, beginning at page 7, you note, "Prior to the</p> <p>4 advent of the modern midurethral sling, traditional</p> <p>5 surgical approaches over the past hundred years have</p> <p>6 included abdominal retropubic urethropexies (Burch,</p> <p>7 the MMK), bladder neck slings, and needle urethral</p> <p>8 suspensions and the Kelly plication"; do you see</p> <p>9 that?</p> <p>10 A Yes.</p> <p>11 Q And with respect to those procedures, do</p> <p>12 all of those procedures have potential risks and</p> <p>13 complications?</p> <p>14 A Definitely.</p> <p>15 Q Do all of those procedures have the risk</p> <p>16 or potential complication of pain?</p> <p>17 A Yes.</p> <p>18 Q Do all of those procedures have the</p> <p>19 potential risk or complication of dyspareunia?</p> <p>20 A Yes.</p> <p>21 Q Did all of those procedures have the risk</p> <p>22 of potential complication of urine retention or</p> <p>23 voiding dysfunction?</p> <p>24 A Yes.</p> <p>25 Q With respect to any of these procedures,</p>

<p style="text-align: right;">Page 154</p> <p>1 is there an IFU that a doctor gets for how to do a 2 Burch procedure? 3 A No. 4 Q Is there an IFU for how to do an MMK? 5 A No. 6 Q Is there an IFU for how to do a needle 7 urethral suspension? 8 A No. 9 Q Is there an IFU for how to do a Kelly 10 plication procedure? 11 A No. 12 Q How is it that doctors learn about or 13 become aware of risks associated with those 14 procedures, which, according to your report, have 15 been around for hundred years if there's no IFU? 16 A Through literature, through clinical 17 experience, through practice. 18 Q Okay. And in your opinion, were doctors 19 able to know about the risks of those procedures 20 based on the factors that you just gave without 21 having an IFU that specifically listed potential 22 risks? 23 A Definitely. 24 Q If you look at the TVT IFU that was marked 25 as Exhibit 8 -- do you have a copy of that?</p>	<p style="text-align: right;">Page 156</p> <p>1 should only be used by physicians trained in the 2 surgical treatment of stress urinary incontinence 3 and specifically in implanting the Gynecare TVT 4 device"; do you see that? 5 A Yes. 6 Q And then the next sentence says, "These 7 instructions are recommended for general use of the 8 device"; do you see that? 9 A Correct. 10 Q Dr. Goldwasser, as a surgeon, do you 11 expect an IFU to be a comprehensive reference for 12 the surgical correction of stress urinary 13 incontinence? 14 A Definitely not. 15 Q Where would you look -- if you were 16 looking for a comprehensive reference for 17 information on adverse events, incidence of adverse 18 events, percentages of adverse events, where would 19 you go to look for that as a physician? 20 A I'd do a literature search. There is no 21 one encompassing reference that embodies all these 22 numbers. 23 Q Dr. Goldwasser, do you agree that there 24 are certain risks that are commonly known to 25 physicians who perform surgical treatment of stress</p>
<p style="text-align: right;">Page 155</p> <p>1 A I do have a copy of -- I had one. Oh, 2 here we go. 3 Q If you'd flip over to the second page, 4 there's a paragraph that says Important; do you see 5 that? 6 A Yeah. 7 Q And important is bolded, correct? 8 A Correct. 9 Q And if you read the -- starting in the 10 second sentence, it says -- or the first sentence 11 talks about it's "a package insert to provide 12 instructions for use on the Tension-free Vaginal 13 Tape single-use device, the Reusable Introducer, and 14 Reusable Rigid Catheter Guide"; do you see that? 15 A Yes. 16 Q So does the document state that, "The 17 design is to provide the instructions for use for 18 using the device"; is that fair? 19 A Yes. 20 Q The second sentence says, "It's not a 21 comprehensive reference to surgical technique for 22 the" correction -- "for correcting stress urinary 23 incontinence"; do you see that? 24 A Yes. 25 Q The next sentence notes, "The device</p>	<p style="text-align: right;">Page 157</p> <p>1 urinary incontinence that apply regardless of the 2 type of surgery that's performed? 3 A Yes. 4 Q Okay. And if a physician is trained in 5 the surgical treatment of stress urinary 6 incontinence, would it be expected that they would 7 be aware of those commonly known risks? 8 A Yes. 9 Q Does the IFU also note that the TVT should 10 be used by doctors who are specifically trained in 11 implanting the TVT device? 12 A Yes. 13 Q And did you actually teach doctors how to 14 use the TVT device? 15 A Yes. 16 Q In your experience, did Ethicon -- if 17 physicians had questions, did you as a preceptor for 18 Ethicon make yourself available to answer questions 19 that other doctors might have about the use of the 20 TVT product? 21 A Definitely. 22 Q If you'll turn to Exhibit 11, which was 23 the article by the -- Colby Perkins is the led 24 author. 25 A Okay.</p>

<p style="text-align: right;">Page 158</p> <p>1 Q If you look in the introduction in the 2 first paragraph, does this article note that, "The 3 current gold standard for the management of stress 4 urinary incontinence is the midurethral sling"? Do 5 you see that? 6 A It's -- yes, correct. 7 Q Based on your knowledge, experience, 8 training, review of the literature, do you agree 9 with that assessment, that, "The current gold 10 standard for the management of stress urinary 11 incontinence is the midurethral sling"? 12 A Definitely. 13 Q If you flip over to the second page on the 14 right-hand column, about two-thirds of the way down, 15 do you see where it notes, "In March 2013, the FDA 16 followed up on their promise to provide more 17 information on the safety of mesh for SUI"? Do you 18 see that? 19 A About a third of the way down -- 20 Q Two-thirds of the way down. 21 A Oh, yeah, okay. 22 Q And does this article note that, "After 23 reviewing the complaints in the MAUDE database, 24 conducting a literature review, and synthesizing the 25 input from the 2011 Obstetrics and Gynecology</p>	<p style="text-align: right;">Page 160</p> <p>1 warning"; do you see that? 2 A Yes. 3 Q Do you recall him referring to that as 4 four separate factors? 5 A Correct. 6 Q Dr. Goldwasser, have you seen in your 7 practice and is it your opinion that part of the 8 lack of clarity around the safety concerns 9 associated with different uses of vaginal mesh was 10 brought about by attorney advertising? 11 A Yes. 12 MR. RESTAINO: Objection. 13 Q And have you seen in your practice and 14 through your discussions with colleagues, has 15 provider fear of litigation been impacted by 16 attorney advertising? 17 A Yes. 18 Q Have you seen in your practice and through 19 your discussions with colleagues media coverage that 20 occurred after the 2011 warning, has that been 21 impacted by attorney advertising? 22 A Yeah. I think it has, yes. 23 Q Okay. So while only one of these factors 24 mentions legal advertising, is it your opinion that 25 legal advertising from plaintiffs' attorneys</p>
<p style="text-align: right;">Page 159</p> <p>1 Devices Panel of the Medical Device Advisory 2 Committee meetings, the FDA determined that the 3 safety and effectiveness of multi-incision slings is 4 well-established in clinical trials that followed 5 patients up to one year"? Do you see that? 6 A Yes. 7 Q Is that information that physicians in 8 your field relied on in determining which products 9 to offer patients? 10 MR. RESTAINO: Objection. 11 A Yeah, I mean, I think that it's definitely 12 helpful in making decisions. 13 Q And is the TVT -- are the TVT and the 14 TVT-Exact, are those multi-incision slings that 15 would have been referenced in this March 2013 -- 16 A Yes. 17 Q -- FDA communication? 18 A Yes. 19 Q Counsel asked you some questions about 20 page 43, the sentence that noted, "The source of 21 this shift may be multifactorial, including provider 22 fear of litigation, lack of clarity around safety 23 concerns associated with the uses of vaginal mesh, 24 and patient fear from legal advertisements, and 25 media coverage that occurred after the 2011</p>	<p style="text-align: right;">Page 161</p> <p>1 contributed to the fear that is reflected in all 2 those categories? 3 MR. RESTAINO: Objection. 4 A Yes. 5 Q And do you believe that that's consistent 6 with this article that you've cited in your report? 7 A Yes. 8 Q Let's take a look at Exhibit 13. Keep 9 that with you, but take a look at Exhibit 13, which 10 is the FDA communication from July 13, 2011. 11 A Okay. 12 Q Dr. Goldwasser, do you agree that the 13 safety concerns that are discussed in this 2011 FDA 14 notification relate to use of mesh for pelvic organ 15 prolapse repair? 16 A Yes. 17 Q Do they discuss complications or adverse 18 events associated with use of mesh for stress 19 urinary incontinence? 20 A I think it's mainly just -- I don't think 21 it mentions stress urinary incontinence, but I think 22 it's really focusing on the pelvic organ prolapse 23 mainly. 24 Q And Counsel read you a statement from this 25 FDA notification that said, "The FDA's issuing this</p>

<p style="text-align: right;">Page 162</p> <p>1 update to inform you that serious complications 2 associated with surgical mesh for transvaginal 3 repair of POP are not rare"; do you recall that? 4 A Correct. 5 Q Would the TVT or the TVT-Exact fit within 6 that sentence? 7 A No. 8 Q Okay. Do you agree that this FDA 9 notification makes clear that the complications that 10 are not rare that's being referred to there is use 11 of mesh for pelvic organ prolapse repair? 12 A Correct. 13 Q Dr. Goldwasser, within even the medical 14 field, are there occasions when doctors will do 15 interviews or be on television programs where 16 perhaps they're not getting paid, but yet they do an 17 interview or part of a television program? 18 A Sure. 19 Q And although that's not paid advertising, 20 is that sometimes used as a means to increase a 21 doctor's profile or to generate publicity and 22 advertising even if it's not paid advertising? 23 MR. RESTAINO: Objection. 24 A Sure. Yes. 25 Q It was a terrible question. Let me</p>	<p style="text-align: right;">Page 164</p> <p>1 review expert reports that were cited -- I mean from 2 plaintiffs' experts? 3 A Yes. 4 Q And have you seen the articles and 5 documents that are referred to in those expert 6 reports? 7 A Yes. 8 Q And did you consider those as you put 9 together your report in formulating your opinions? 10 A Yes. 11 Q And as you sit here today, even after 12 questioning by Counsel, you still hold the opinions 13 set forth in your report to a reasonable degree of 14 medical certainty? 15 A Yes. 16 MR. RUMANEK: That's all the questions 17 I've got. 18 REDIRECT EXAMINATION 19 BY MR. RESTAINO: 20 Q Doctor, working backwards, does the Koo 21 article mention anywhere interviews with attorneys? 22 A Koo article. I don't recall off the top 23 of my head, but -- here we are. Would you like me 24 to go through and read it? 25 Q If you need to glance through it or if you</p>
<p style="text-align: right;">Page 163</p> <p>1 rephrase that. 2 Can -- are there instances when doctors 3 will use media interviews with newspapers or 4 television stations where they're not being paid as 5 a means of advertising for their practice and their 6 expertise? 7 A Yes. 8 Q And have you also seen -- let me strike 9 that. 10 Is it also possible -- looking at Exhibit 11 12, which is the Koo study, and we don't have the 12 media things that mentioned litigation -- the media 13 articles that mentioned litigation here, but do you 14 agree that it's possible that when attorneys are 15 interviewed or when things can -- that there can be 16 a discussion of litigation within newspapers that is 17 not paid advertising but can help generate publicity 18 or referrals for attorneys? 19 A Yes. 20 Q And in your report where you talk about 21 the advertising campaign that occurred, were you 22 limiting that only to paid television commercials? 23 A No, just in general. 24 Q Dr. Goldwasser, as part of your review of 25 materials in these cases, have you had occasion to</p>	<p style="text-align: right;">Page 165</p> <p>1 want to look at the methodology where they describe 2 exactly what it is that they did. 3 MR. RUMANEK: And I just -- it does note 4 paid advertisements are included. Oh, I'm 5 sorry, it says were excluded. Strike that. 6 A Rephrase your question again. 7 Q Is there any evidence in the methodology 8 or in the entire study that they utilized paid or 9 unpaid attorney interviews as part of their 10 methodology? 11 A It does not specifically mention that. 12 Q The very last page and last paragraph of 13 the Koo article -- 14 A The same article. 15 Q -- I'm sorry, the very last paragraph 16 specifically states, "This study did not assess 17 advertisements and non-news sources of information 18 about transvaginal mesh, particularly those related 19 to litigation." Did I read that correctly? 20 A You're looking under Conclusions or are 21 you looking at the last paragraph? 22 Q I'm sorry, right above Conclusions. 23 Forgive me. I'm sorry. 24 A Yes, yes. I see it. 25 Q So any testimony regarding paid or unpaid</p>

<p style="text-align: right;">Page 166</p> <p>1 attorney interviews in news reports or wherever is 2 just speculation, wouldn't you agree? 3 MR. RUMANEK: Object to the form. 4 A Yes, it does not specifically mention 5 those citations, correct. 6 Q Now, the 2011 FDA safety announcement, as 7 pointed out by Counsel and specifically within the 8 report itself, the title of the safety announcement 9 is specifically for pelvic organ prolapse, correct? 10 A Correct. 11 Q And, in fact, in the second page above the 12 bold underlined verbiage, it specifically says that, 13 "The FDA continues to evaluate the effects of using 14 surgical mesh to repair SUI and will communicate 15 these findings at a later date," period, correct? 16 A Correct. 17 Q So there's no intent to use this for 18 purposes of midurethral slings -- slings or 19 incontinence at this time, correct? 20 A I don't understand your question. 21 Q The FDA's intent here is not to provide 22 data on SUI, but as it says in the title, it's 23 strictly for pelvic organ prolapse? 24 A Correct. 25 Q Okay. And there was no intent on my part</p>	<p style="text-align: right;">Page 168</p> <p>1 MR. RUMANEK: Back on the record. 2 BY MR. RESTAINO: 3 Q Let me reask my question, try to make it a 4 little bit more clearer. Does this article at all 5 that you've cited and you rely upon discuss 6 interviews, paid or unpaid, of attorneys within news 7 stories? 8 A I don't know that it specifically 9 discusses that. 10 Q Now, when you're asked about the lack of 11 clarity around safety concerns associated with 12 different uses of vaginal mesh, you don't know the 13 basis for which these authors are relying upon when 14 they say lack of clarity around safety concerns, do 15 you? 16 A I'm simply going by my reading of this 17 article and my clinical experience and patient 18 perceptions. 19 Q Would you agree, though, it's speculating 20 as to whether or not the lack of clarity is due to 21 legal advertisements when legal advertisements is 22 then specifically mentioned as the next factor in 23 this multifactorial model? 24 MR. RUMANEK: Object to the form. 25 A I'm not sure I'm following you. I mean,</p>
<p style="text-align: right;">Page 167</p> <p>1 to use it for SUI, it was introductory to the Koo 2 article, which is about this update -- 3 MR. RUMANEK: Object -- 4 Q -- you understand that? 5 MR. RUMANEK: -- to form. 6 A Okay. Yes, I see transition, okay. 7 Q And then you were asked some questions 8 about the Perkins study also. And again, regarding 9 Perkins, is there any evidence whatsoever that 10 interviews with attorneys, paid or unpaid, in any 11 way contributed to the wave of anxiety? 12 A I'm looking for that. Which -- what 13 exhibit is that? 14 MR. RUMANEK: Exhibit 11. 15 A All right. Let's see. Can you repeat 16 that question again? 17 Q Yes. Does -- does the Perkins study 18 itself talk about unpaid or paid attorney 19 interviews? 20 A I would have to read through and read the 21 methods, but I don't -- 22 MR. RUMANEK: Can we go off the record for 23 just a minute? 24 MR. RESTAINO: Sure. 25 (Off-the-record discussion.)</p>	<p style="text-align: right;">Page 169</p> <p>1 they mention over here -- they mention here fear of 2 litigation and they mention legal issues being 3 potentially a lack of -- the way it's interpreted by 4 people is being a lack of clarity, but I'm not sure 5 I follow you. Repeat it. 6 Q They specifically state in the next page 7 patient fear from legal advertisements. 8 A Right. 9 Q They do not specifically say lack of 10 clarity around safety concerns as a result of legal 11 advertisements, do they? 12 A That's my interpretation. 13 Q Okay. And right after everything we read 14 on the right-hand column, the very first full 15 paragraph, they actually then state, "Law experts 16 have indicated that the lack of appropriate informed 17 consent is the most likely reason that a provider 18 would be named in a mesh lawsuit"; do you see that? 19 A Correct. 20 Q And would you agree that that's generally 21 known within the medical community, that lack of 22 informed consent is a primary reason for physicians 23 being sued? 24 A Not -- it's hard to say. 25 Q Okay. Regarding provider fear of</p>

<p style="text-align: right;">Page 170</p> <p>1 litigation, as a result of the current environment</p> <p>2 that is multifactorial, do you share the known</p> <p>3 adverse events associated with your -- the mesh</p> <p>4 product with your patients prior to surgery so they</p> <p>5 can make an informed decision as to whether or not</p> <p>6 to have the surgery?</p> <p>7 MR. RUMANEK: Object to the form.</p> <p>8 A Yes. Yes.</p> <p>9 Q Do you think that's a good thing that you</p> <p>10 do?</p> <p>11 A I think it's -- it's a double-edged sword</p> <p>12 because I think it can provide -- it can cause some</p> <p>13 fear where it's not necessarily warranted, but at</p> <p>14 the same time, it's providing information for</p> <p>15 decisions.</p> <p>16 Q The Exhibit 8 that you were asked about,</p> <p>17 which is the TVT IFU, at the conclusion of a</p> <p>18 residency and especially at the conclusion of a</p> <p>19 residency and fellowship, do you know of any surgeon</p> <p>20 that then would read an IFU for how to do a</p> <p>21 procedure?</p> <p>22 A No.</p> <p>23 Q You learn that in training -- hands-on</p> <p>24 training with your attendings and then with</p> <p>25 experience, correct?</p>	<p style="text-align: right;">Page 172</p> <p>1 possibly peer-reviewed data, but there is also</p> <p>2 information available from the people who have been</p> <p>3 using it potentially in the study. I think there's</p> <p>4 a lot of information out there that's not</p> <p>5 necessarily just contained in published studies.</p> <p>6 There's meetings, there's colleague discussions and</p> <p>7 so forth.</p> <p>8 Q But the meetings and discussions can only</p> <p>9 talk about the safety and efficacy from the clinical</p> <p>10 trials that has been reported either by the</p> <p>11 investigators themselves or by the manufacturer,</p> <p>12 correct?</p> <p>13 MR. RUMANEK: Object to the form.</p> <p>14 A Yeah, typically meetings. I mean, you're</p> <p>15 going to be looking at studies that were set up to</p> <p>16 look at this specifically, but I don't necessarily</p> <p>17 know that all that information -- that</p> <p>18 information -- I wouldn't anticipate all that</p> <p>19 information necessarily being contained in an IFU.</p> <p>20 Q Okay. Looking at the adverse reactions</p> <p>21 here for this product on page 5, as we've discussed</p> <p>22 during my time in questioning, the device has been</p> <p>23 associated with voiding dysfunction, using your</p> <p>24 definition, correct?</p> <p>25 A Let's see.</p>
<p style="text-align: right;">Page 171</p> <p>1 A Correct.</p> <p>2 Q Experience is that thing you get right</p> <p>3 after you needed it.</p> <p>4 But if you turn to the fifth page, they do</p> <p>5 have a heading for Adverse Reactions, correct?</p> <p>6 A Correct.</p> <p>7 Q And for any new device that comes on the</p> <p>8 market, would you as a surgeon before you implanted</p> <p>9 it in your patient, would you want to know of the</p> <p>10 clinically significant known adverse reactions?</p> <p>11 A I think that it's a good idea to have a</p> <p>12 general awareness of the device you're using, the</p> <p>13 indications for it, some of the consequences, but</p> <p>14 again, I don't rely necessarily on the IFU to</p> <p>15 provide all that. I think it's just part of the --</p> <p>16 of the world in which you live. You get information</p> <p>17 from multiple sources and you put it together to</p> <p>18 form conclusions.</p> <p>19 Q If a medical device such as TVT-Exact is</p> <p>20 released on January 1st of a year, would you agree</p> <p>21 that at that point, the only data available as to</p> <p>22 its safety and efficacy would be from the published</p> <p>23 results of the clinical trials?</p> <p>24 MR. RUMANEK: Object to the form.</p> <p>25 A The only data available. The only</p>	<p style="text-align: right;">Page 173</p> <p>1 Q I'm just saying generally we discussed the</p> <p>2 fact that voiding dysfunction has been reported with</p> <p>3 this device, correct?</p> <p>4 A As with all procedures for incontinence,</p> <p>5 correct.</p> <p>6 Q Voiding dysfunction is not listed as an</p> <p>7 adverse reaction with this procedure in the IFU, is</p> <p>8 it?</p> <p>9 MR. RUMANEK: Object to the form.</p> <p>10 A Well, it's my understanding too that one</p> <p>11 of the exclusions is commonly known adverse</p> <p>12 reactions to procedures like this don't necessarily</p> <p>13 need to be contained in an IFU.</p> <p>14 So, for example, voiding dysfunction is</p> <p>15 common to all incontinence procedures. And in</p> <p>16 looking at randomized controlled studies, voiding</p> <p>17 dysfunction is actually higher in non-midurethral</p> <p>18 sling procedures. So relatively speaking, this is</p> <p>19 less likely to cause voiding dysfunction.</p> <p>20 But back to the bigger point is that it's</p> <p>21 a known ramification of any surgery for</p> <p>22 incontinence, and so it's my understanding it</p> <p>23 doesn't necessarily need to be discussed here</p> <p>24 because it's a known factor.</p> <p>25 Q Okay. Now, in addition to known factors,</p>

<p style="text-align: right;">Page 174</p> <p>1 as we discussed, bladder perforation is a known 2 complication of pelvic surgery -- 3 A Correct. 4 Q -- correct? And yet we looked at the 5 Brubaker study where the -- where the -- there was a 6 study -- significant increased risk of bladder 7 perforation, and I believe that was the one that was 8 5 percent versus zero, though the record speaks for 9 itself, the bladder perforation is not listed as an 10 adverse reaction, is there? 11 MR. RUMANEK: Object to the form. 12 A It is. It says, "Punctures or lacerations 13 of vessels, nerves, bladder, or bowel" in number -- 14 the first bullet under Adverse Reactions. 15 Q Ah, okay. Yes, I see that. 16 The incidence of each of these 17 complications is not listed, correct? 18 A In each study there was different reported 19 incidence, so there's no way that -- there's no one 20 solitary number that represents the number of 21 adverse events for any event. It's all study 22 dependent. 23 Q But the studies occur -- multiple studies 24 occur once a product is available for mass 25 marketing. The -- I was trying to get to the fact</p>	<p style="text-align: right;">Page 176</p> <p>1 trials. Wouldn't that depend on the quality of the 2 underlying randomized controlled trials? 3 A Correct. I mean, what you put into it 4 is -- 5 Q Are you familiar with the word 6 "heterogenicity"? 7 A Correct. 8 Q So if we're looking at, and I believe 9 Counsel used the example, the Burch procedure, that 10 doesn't involve mesh, does it? 11 A No. 12 Q If one's looking at complication rates of 13 Burch versus mesh, that's a different study than 14 mesh -- a comparator of mesh versus mesh, would you 15 agree? 16 A Correct. 17 Q Now, if we have 20 small, poorly designed 18 randomized controlled trials with high level of 19 heterogenicity, that meta-analysis is going to 20 reproduce that weak evidence, correct? 21 MR. RUMANEK: Object to the form. 22 A It could, but in this case, there are some 23 large, good quality randomized controlled trials 24 that have been subject to meta-analysis and 25 systematic reviews. So it depends --</p>
<p style="text-align: right;">Page 175</p> <p>1 that on day one, when the device is released, at 2 that time the only data that's available is that 3 data done in the premarketing clinical trials, would 4 you agree? 5 MR. RUMANEK: Object to the form. 6 A Potentially. 7 Q And based upon that data, the incidence 8 rate is not listed, correct? 9 MR. RUMANEK: Object to the form. 10 A It's not listed here, correct. 11 Q And so, therefore, you as a surgeon, if 12 there was, in fact, a 15 percent increased risk of 13 bowel perforation, you, with your training and 14 experience, know that's markedly higher than I would 15 expect with any pelvic procedure, wouldn't you want 16 to know that? 17 MR. RUMANEK: Object to the form. 18 A Not necessarily in this form. 19 Q Okay. Okay. And then finally, I believe 20 you said, I'll paraphrase because I don't remember 21 your exact words, but that you consider the 22 meta-analysis to be the highest form of 23 epidemiological evidence. 24 A Of randomized clinical trials, correct. 25 Q Meta-analysis of randomized controlled</p>	<p style="text-align: right;">Page 177</p> <p>1 Q My -- 2 A It depends on -- 3 Q I'm sorry. 4 A Yes, what you include in a meta-analysis, 5 you know, affects the results of the meta-analysis. 6 Q So the term -- leading to the term 7 "garbage in, garbage out"? 8 A Correct, but there are good meta-analyses 9 of the retropubic sling procedure. 10 MR. RESTAINO: Yes. 11 MR. RUMANEK: I've just got one question. 12 RECROSS EXAMINATION 13 BY MR. RUMANEK: 14 Q Dr. Goldwasser, you've cited in your 15 report on page 20- -- and are familiar with the 16 AUG/SUFU position statement? 17 A Yes. 18 Q Looking at page 21, one of the bullet 19 points that you've cited, I'll just read it, "The 20 monofilament polypropylene mesh midurethral sling is 21 the most extensively studied anti-incontinence 22 procedure in history. A broad evidence base, 23 including high quality scientific papers and medical 24 journals in the U.S. and the world, supports the use 25 of midurethral sling as a treatment of stress</p>

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1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC., PELVIC REPAIR
5 SYSTEM PRODUCTS LIABILITY Master File No. 2:12-MD-02327
6 LITIGATION MDL No. 2327
7
8 THIS DOCUMENT RELATES TO ALL
9 WAVE 5 AND SUBSEQUENT WAVES
10 CASES AND PLAINTIFFS:
11
12 Debbie Avant
13 Case No. 2:12-cv-07413
14 Patricia Bell
15 Case NO. 2:12-cv-06750
16
17 Patsy Frame
18 Case No. 2:12-cv-07524
19 Patricia Hosbrook
20 Case No. 2:12-cv-07843
21
22 Mary Alice Landeche
23 Case No. 2:12-cv-07962
24
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